

## **Mentions of Patent-Related Compulsory Licenses in Special 301 Reports 1998-2017**

### **2017 Special 301 Report**

#### *Indonesia: Priority Watch List*

In addition, revisions to Indonesia's Patent Law in July 2016 have raised concerns, including with respect to the patentability criteria for incremental innovations and computer implemented inventions; local manufacturing and use requirements; **the grounds and procedures for issuing compulsory licenses**; disclosure requirements for inventions related to traditional knowledge and genetic resources; and requirements to disclose the details of private licensing agreements. As Indonesia enacts implementing regulations for the revised Patent Law, the United States continues to urge Indonesia to address these concerns and to provide affected stakeholders with meaningful opportunities for input.

#### *India: Priority Watch List*

Certain national policies and practices advanced domestically and in multilateral fora may have the effect of undermining innovation needed to address serious environmental challenges. For example, **India's** National Manufacturing Policy promotes the compulsory licensing of patented technologies as a means of technology transfer with respect to green technologies. Such policies, which India has sought to multilateralize in United Nations (UN) negotiations, will discourage, rather than promote, investment in and dissemination of green technology innovation, including those technologies that contribute to climate change adaptation and mitigation.

Innovative companies remain concerned about the potential threat posed to their IP through the possible use of compulsory licensing and patent revocation, as well as overly broad criteria for issuing such licenses and revocations under the India Patents Act.

#### *Turkey: Watch List*

However, the law [Industrial Property Law No. 6769] also introduces new challenges, including in the area of compulsory licensing, while failing to resolve some longstanding issues that would significantly improve its IP regime.

### **2016 Special 301 Report**

#### *Indonesia: Priority Watch List*

The United States also remains concerned about the lack of clarity surrounding legal procedures under the Indonesian patent law in connection with the grant of compulsory licenses. The United States encourages Indonesia to provide for judicial or other independent review of any compulsory license authorizations.

### *India: Priority Watch List*

Certain national policies and practices advanced domestically and in multilateral fora may have the effect of undermining innovation needed to address serious environmental challenges. For example, India's National Manufacturing Policy promotes the compulsory licensing of patented technologies as a means of effectuating technology transfer with respect to green technologies. Such policies, which India has sought to multilateralize in United Nations (UN) negotiations, will discourage, rather than promote, investment in and dissemination of green technology innovation, including those technologies that contribute to climate change adaptation and mitigation.

India has also not taken the opportunity to address longstanding challenges that represent significant IPR regime deficiencies compared to other markets. The pharmaceutical industry in particular faces a host of challenges related to IPR. These include ... lack of clarity on standards for Sections 85 and 92 compulsory licenses ... . Furthermore, "Form 27" requires patent holders to provide detailed information on an annual basis that is used by the patent office to determine whether a patent is sufficiently worked in India. Patentees thus face the serious consequence of possibly having their patent revoked or subject to a compulsory license if they fail to meet the standard.

While emphasizing our continued commitment to the Doha Declaration on the TRIPS Agreement and Public Health, (see **Intellectual Property and Health**), the United States also continues to monitor India's application of its compulsory licensing law. The United States requests clarity from the Government of India regarding the compulsory license decision-making process, as it affects U.S. stakeholders. In particular, the United States requests further clarification that could increase confidence for patentees such that they better understand the conditions for which a compulsory license would be permitted. Although the government has issued only one compulsory license under Section 84 of India's Patents Act and recently rejected another Section 84 petition, India has made clear in other policy statements that it views compulsory licensing as an important tool of industrial policy for green technologies, with the potential to be applied more regularly across economic sectors. Specifically, India has, in the past, promoted compulsory licensing in its National Manufacturing Policy as a mechanism available for government entities to effectuate technology transfer in the clean energy sector. More recently, an April 2015 draft of what the media reported to be an updated copy of the National IPR Policy included a call for "the acquisition of environment- friendly technologies through voluntary and involuntary licensing, creation of patent pools, technology transfer, and other business collaboration arrangements." ... In addition, the Indian Intellectual Property Appellate Board's interpretation of Section 84 of India's Patents Act suggests that a patent could be subject to a compulsory license if the patented product is not manufactured in India.

### *Ecuador: Watch List*

Finally, the United States encourages Ecuador to provide clarification on its processes related to the compulsory licensing of pharmaceuticals.

## **2015 Special 301 Report**

### *Indonesia: Priority Watch List*

The United States remains concerned about the lack of clarity surrounding legal procedures under the Indonesian patent law in connection with the grant of compulsory licenses. The United States encourages Indonesia to provide for judicial or other independent review of any compulsory license authorizations. P. 44.

### *India: Priority Watch List*

Certain national policies and practices advanced domestically and in multilateral fora may have the unintended effect of undermining national and global efforts to address serious environmental challenges. For example, India's National Manufacturing Policy promotes the compulsory licensing of patented technologies as a means of effectuating technology transfer with respect to green technologies. India has pressed to multilateralize this approach through its proposals in the negotiations under the United Nations Framework Convention on Climate Change (UNFCCC). These actions will discourage, rather than promote, investment in and dissemination of green technologies, including those technologies that contribute to climate change adaptation and mitigation.

Second, while emphasizing our continued commitment to the Doha Declaration on the TRIPS Agreement and Public Health, as discussed in the Intellectual Property and Health section of this Report (See Section I), the United States also continues to monitor India's application of its compulsory licensing law. The United States requests clarity from the Government of India regarding the compulsory license decision-making process as it affects U.S. stakeholders. Although the government has issued only one compulsory license under Section 84 of India's Patents Act, India has made clear in other policy statements that it views compulsory licensing as an important tool of industrial policy for green technologies, with the potential to be applied more regularly across economic sectors. Specifically, India has, in the past, promoted compulsory licensing in its National Manufacturing Policy as a mechanism available for government entities to effectuate technology transfer in the clean energy sector.

The United States requests clarity from the Government of India regarding the compulsory license decision-making process as it affects U.S. stakeholders. Although the government has issued only one compulsory license under Section 84 of India's Patents Act, India has made clear in other policy statements that it views compulsory licensing as an important

tool of industrial policy for green technologies, with the potential to be applied more regularly across economic sectors. Specifically, India has, in the past, promoted compulsory licensing in its National Manufacturing Policy as a mechanism available for government entities to effectuate technology transfer in the clean energy sector. ... companies. In addition, the Indian Intellectual Property Appellate Board's interpretation of Section 84 of India's Patents Act suggests that a patent could be subject to a compulsory license if the patented product is not manufactured in India.

#### *Ecuador: Priority Watch List*

Finally, the United States encourages Ecuador to provide clarification on its processes related to the compulsory licensing of pharmaceuticals.

### **2014 Special 301 Report**

#### *Indonesia: Priority Watch List*

The United States remains concerned by Indonesian government statements indicating that Indonesia failed to abide by Indonesian legal procedures in issuing a compulsory license decree in 2012 and indicating that Indonesian patent law does not require individual merits review in connection with the grant of compulsory licenses. The United States further encourages Indonesia to provide for judicial or other independent review of any compulsory license authorizations. The United States looks forward to working with Indonesia on these and other matters.

#### *India: Priority Watch List*

Certain national policies and practices advanced domestically and in multilateral fora may have the unintended effect of undermining national and global efforts to address serious environmental challenges. For example, India's National Manufacturing Policy promotes the compulsory licensing of patented technologies as a means of effectuating technology transfer with respect to green technologies. India has pressed to multilateralize this approach to green technologies through its proposals in the negotiations under the United Nations Framework Convention on Climate Change (UNFCCC). These actions will discourage rather than promote the investment in, and dissemination of, green technologies, including those technologies that contribute to climate change adaptation and mitigation.

Second, while bearing in mind the Doha Declaration on TRIPS and Public Health, discussed in the Intellectual Property and Health Policy section of this Report, the United States also continues to monitor developments concerning compulsory licensing of patents in India. The United States urges India to provide greater transparency about its ongoing inter-ministerial process that is considering over a dozen patented medicines as candidates for

government- initiated compulsory licenses, and urges India to allow opportunities for input by rights holders, as appropriate, with respect to decisions concerning compulsory licenses.

In addition, the United States continues to be concerned with the rationale underlying a decision by India's Controller-General of Patents to grant a compulsory license under Section 84 of India's Patents Act (which allows private parties to initiate proceedings seeking a compulsory license of a patented article), as upheld by a recent judgment of the IPAB. The grant of the compulsory license was based, in part, on the innovator's failure to "work" the patent in India because it imported its products, rather than manufacturing them in India. The United States recognizes that, on appeal, the IPAB modified the Controller-General's reasoning to clarify that "in some cases" the "working" requirement could be met solely by importation. The IPAB, however, rejected the innovator's explanation that economic factors prevented manufacturing in India, stating, "the patentee must show why it could not be locally manufactured. A mere statement to that effect is not sufficient[,] there must be evidence."<sup>3</sup> The IPAB did not clarify the circumstances under which the "working" requirement would be met without manufacturing in India. The decision could inappropriately pressure innovators outside of India – including those in sectors well beyond pharmaceuticals, such as green technology and information and communications technology – to manufacture in India in order to avoid being compelled to license an invention to third parties. The IPAB's decision is currently on appeal to the Bombay High Court.

Although the government has issued only one compulsory license under Section 84, India has made clear that it views compulsory licensing as an important tool of industrial policy for green technologies, with the potential to be applied more regularly across economic sectors. Specifically, India has promoted compulsory licensing in its National Manufacturing Policy as a mechanism available for government entities to effectuate technology transfer in the clean energy sector. India similarly has sought to multilateralize this approach in ongoing negotiations under the UNFCCC. In those negotiations India continues to identify patents as obstacles to the dissemination of climate change technologies, pressing for outcomes that would potentially undermine incentives for innovation, such as existing global standards for patent protection that is a critical part of the response to climate change and other environmental challenges.

In addition, as noted above, the IPAB's interpretation of Section 84 of India's Patents Act suggests that a patent could be subject to a compulsory license if it is not manufactured in India.

## 2013 Special 301 Report

### *Indonesia: Priority Watch List*

The United States notes with concern statements in Indonesia's Special 301 submission indicating that Indonesia failed to abide by its procedures in issuing a compulsory license decree in 2012, and that its patent law does not require individual merit review in connection with the grant of compulsory licenses. The United States further encourages Indonesia to provide for judicial or other independent review of any compulsory license authorizations. The United States looks forward to working with Indonesia on these and other matters.

### *India: Priority Watch List*

The United States will also continue to monitor closely developments concerning compulsory licensing of patents in India, particularly following the broad interpretation of Indian law in a recent decision by the Indian Intellectual Property Appellate Board (IPAB), while also bearing in mind the Doha Declaration on TRIPS and Public Health, discussed in the Intellectual Property and Health Policy section of this Report. In particular, India's decision in this case to restrict patent rights of an innovator based, in part, on the innovator's decision to import its products, rather than manufacture them in India, establishes a troubling precedent. Unless overturned, the decision could potentially compel innovators outside India – including those in sectors well beyond pharmaceuticals, such as green technology and information and communications technology – to manufacture in India in order to avoid being forced to license an invention to third parties.

## 2012 Special 301 Report

### *China: Priority Watch List*

In 2011, China's State Intellectual Property Office (Sipo) issued "Draft Measures for Compulsory Licensing of Patents" for public comments. These measures are intended to provide greater guidance to Sipo, patent holders, and individuals and entities that seek the grant of a compulsory license under China's Patent Law. The United States appreciates that Sipo provided an opportunity for interested stakeholders to comment upon the draft. A number of companies and governments, including the United States, provided comments on these measures, raising concerns ranging from the length of time provided for certain procedural steps, to substantive concerns regarding the scope and grounds for the application of a compulsory license. On March 19, Sipo issued a slightly revised document, dated March 15, 2012, with indications that the document will go into effect on May 1, 2012. The United States is concerned that many stakeholder concerns were not reflected in the final document. The United States looks forward to working with stakeholders and the Government of China to ensure that the implementation of these measures is consistent

with China's international obligations and does not unfairly disadvantage foreign patent holders, including through further amendments to the measure if necessary.

#### *India: Priority Watch List*

The United States will closely monitor developments concerning compulsory licensing of patents in India following the broad interpretation of Indian law in a recent decision by the Controller General of Patents, while also bearing in mind the Doha Declaration on TRIPS and Public Health found in the Intellectual Property and Health Policy section of this Report.

### **2011 Special 301 Report**

#### *China: Priority Watch List*

In November 2009, SAC circulated a new draft of the Provisional Regulations for public comment. This draft measure would implement China's vision for a standards development process and establish the general principle that mandatory national standards should not incorporate patented technologies. However, the draft measures provide that when mandatory national standards incorporate patented technologies, there is the possibility of a compulsory license if a patent holder does not grant a royalty-free license. This differs from the typical practice of accredited standards developing organizations in other countries, which require disclosure of intellectual property in the standards development process and support "reasonable and nondiscriminatory" (RAND) licensing policies with respect to intellectual property that is incorporated into a standard. RAND policies require concerned patent rights holders to make any intellectual property incorporated into the standards that these bodies develop available to all interested parties on RAND terms. Within the standards development process, licensing terms are typically negotiated between the right holder and parties interested in implementing the standards.

#### *Ecuador: Watch List*

The United States will continue to monitor developments concerning compulsory licensing of pharmaceutical and agricultural chemical products in Ecuador, bearing in mind the discussion of the Doha Declaration on TRIPS and Public Health in Section I of this Report.

### **2010 Special 301 Report**

#### *China: Priority Watch List*

Draft Regulations for the Administration of the Formulation and Revision of Patent-Involving National Standards, released for public comment in November 2009 by the

Standardization Administration of China (SAC), raise concerns regarding their expansive scope, the feasibility of certain patent disclosure requirements, and the possible use of compulsory licensing for essential patents included in national standards. If adopted in their current form, these provisions may have the unintended effect of undermining the incentives for innovation and, by discouraging foreign rights holders from participating in the development of standards in China, depriving the standard setting process of potentially superior technology.

With respect to patents, on October 1, 2009, the Third Amendment to China's Patent Law, passed in December 2008, went into effect. While many provisions of the Patent Law were clarified and improved, rights holders have raised a number of concerns about the new law and implementing regulations, including the effect of disclosure of origin requirements on patent validity, inventor remuneration, and the scope of and procedures related to compulsory licensing, among other matters. The United States will closely follow the implementation of these measures in 2010.

#### *Ecuador: Watch List*

The United States will continue to monitor recent developments concerning compulsory licensing of pharmaceutical and agricultural chemical products in Ecuador, bearing in mind the discussion of the Doha Declaration on TRIPS and Public Health in Section I of this report.

### **2009 Special 301 Report**

#### *China: Priority Watch List*

The Chinese Government is currently considering legal and/or policy changes in areas such as the scope of compulsory licensing of patented inventions, the treatment of IPR in setting standards, and other areas that have the potential to affect IPR protection and market access for IPR-reliant goods and services. The United States will monitor these developments closely to ensure fair and equitable treatment for U.S. rights holders.

China enacted the Third Amendment to its Patent Law in 2008. ... Also, there are concerns ... about the scope and role of compulsory licensing under the new law.

#### *Thailand: Priority Watch List*

The United States is also encouraged by Thailand's expressed intentions to reduce the uncertainty created by the previous Government's policies concerning the issuance of compulsory licenses on patented pharmaceutical products. As affirmed in the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health, the United States respects a country's right to protect public health and, in particular, to promote access to medicines

for all. In this regard, the United States respects a country's right to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement. Consistent with these views, we urge Thailand to consider ways of addressing its public health challenges while maintaining a stable patent system that promotes investment, research, and innovation.

## 2008 Special 301 Report

### *China: Priority Watch List*

Concerns have been raised regarding draft amendments to the Patent Law that were recently made available for public comment on issues such as: the role of compulsory licensing; ...

### *Thailand: Priority Watch List*

While the United States recognizes the importance of Thailand's public health challenges, Thailand's recent policies and actions regarding the compulsory licensing of patented medicines have contributed to continuing concerns regarding the adequate and effective protection of IPR in Thailand.

## 2007 Special 301 Report

### *China: Priority Watch List*

Such concerns are especially acute in light of Chinese government policies establishing a procurement preference for domestically innovated products, statements and consideration of legal changes regarding such areas as compulsory licensing and the use of IPR in setting standards ... .

### *Thailand Priority Watch List*

In addition to these longstanding concerns with deficient IPR protection in Thailand, in late 2006 and early 2007, there were further indications of a weakening of respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products. While the United States acknowledges a country's ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern.

### *Brazil Watch List*

The Brazilian Government has at times indicated consideration of the use of compulsory licensing on patented pharmaceutical products. The United States underscores the

importance of Brazil engaging in open and transparent discussions with all relevant stakeholders in such cases, in the interest of reaching mutually satisfactory outcomes.

## 2006 Special 301 Report

### *China: Priority Watch List*

Such concerns are especially relevant in light of recently issued Chinese government policies establishing a procurement preference for domestically innovated products, statements and consideration of legal changes regarding such areas as compulsory licensing and the use of IPR in setting standards . . . .

## 2005 Special 301 Report

None re patents

## 2004 Special 301 Report

### *Dominican Republic*

In addition, U.S. concerns regarding the patent provisions of the Industrial Property Law and the subsequent Presidential decrees remain. These concerns include, but are not limited to, issues regarding the issuance of compulsory licenses.... .

## 2003 Special 301 Report

None re patents

## 2002 Special 301 Report

### *Brazil: Priority Watch List*

The 2000 Special 301 report announced our initiation of a WTO dispute against Brazil over a longstanding issue between the two countries regarding Article 68 (1) (I) of Brazil's patent law, which requires all patent owners to manufacture their patented products in Brazil or else be subject to the compulsory licensing of their patents. This appears to be in violation of TRIPS Article 27.1, which prohibits Members of the WTO from discriminating on the basis of "...whether the products are imported or locally produced." The United States continues to question whether such a requirement is consistent with Brazil's obligations under the TRIPS Agreement. In June 2001 the United States and Brazil reached an agreement to transfer our dispute to a newly formed U.S.-Brazil Bilateral Consultative Mechanism. Under the Consultative Mechanism, the United States will receive advance notice from the

Government of Brazil should it decide to use Article 68 (1) (I). The United States has fully reserved all of its WTO rights in this matter. The establishment of the Consultative Mechanism is a step forward in resolving this dispute with Brazil.

#### *India: Priority Watch List*

India fails to provide patent protection for pharmaceutical and agricultural chemical products and the compulsory licensing system seems overly broad.

### **2001 Special 301 Report**

#### *Brazil Priority Watch List*

The 2000 Special 301 report announced U.S. initiation of a WTO dispute against Brazil over a longstanding issue between the two countries regarding Article 68 of Brazil's patent law, which requires all patent owners to manufacture their patented products in Brazil or else be subject to the compulsory licensing of their patents. This appears to be in violation of TRIPS Article 27.1, which prohibits Members of the WTO from requiring the local production of the patented invention as a condition for enjoying exclusive patent rights. This issue has been unresolved for more than five years, therefore, the United States decided to resort to WTO dispute settlement procedures. Despite numerous consultations, a mutually acceptable resolution could not be reached. On February 1, 2001, a WTO panel was established. Since the establishment of this panel, however, Brazil has asserted that the U.S. case will threaten Brazil's widely-praised anti-AIDS program, and will prevent Brazil from addressing its national health crisis. Nothing could be further from the truth. For example, should Brazil choose to compulsory license anti-retroviral AIDS drugs, it could do so under Article 71 of its patent law, which authorizes compulsory licensing to address a national health emergency, consistent with TRIPS, and which the United States is not challenging. In contrast, Article 68 -- the provision under dispute -- may require the compulsory licensing of any patented product, from bicycles to automobile components to golf clubs. Article 68 is unrelated to health or access to drugs, but instead is discriminating against all imported products in favor of locally produced products. In short, Article 68 is a protectionist measure intended to create jobs for Brazilian nationals.

#### *Egypt Priority Watch List*

Egypt's patent law also does not appear to comply with TRIPS. It ... has overly-broad compulsory licensing provisions.

#### *India Priority Watch List*

India fails to provide patent protection for pharmaceutical and agricultural chemical products and the compulsory licensing system seems overly broad.

### *Uruguay Priority Watch List*

While new patent legislation was recently passed, it also contains major flaws, including ... overly-broad compulsory license provisions ... .

## **2000 Special 301 Report**

### *Uruguay Priority Watch List*

1999 Special 301 Report

### *Argentina Priority Watch List*

The Argentine patent regime, which contains onerous compulsory licensing provisions ... .

### *Dominican Republic Priority Watch List*

### *Egypt Priority Watch List*

### *Kuwait Priority Watch List*

### *South Africa Watch List*

### *Uruguay Watch List*

## **1998 Special 301 Report**

### *Argentina Priority Watch List*

Argentina's patent law contains onerous compulsory licensing provisions ... .

### *Egypt Priority Watch List*

Egypt lacks adequate patent protection for pharmaceuticals. The current law excludes pharmaceutical products from patentability and contains overly broad compulsory licensing provisions.

### *Honduras Watch List*

The term of protection in the patent law does not meet international standards, it contains overly broad compulsory licensing provisions, ... .