

Statement of

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on

“INTERNATIONAL PATENT ISSUES: PROMOTING A LEVEL PLAYING
FIELD FOR AMERICAN INDUSTRY ABROAD”

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Chairman Goodlatte, Ranking Member Watt and Members of the Subcommittee, I appreciate the opportunity to appear before you to discuss the promotion and protection of American intellectual property overseas and specifically, to examine challenges and barriers presented to American companies when they seek patent protection in key markets.

(Please note that this statement reflects my own personal views and is not given on behalf of my firm or any of its clients.)

I. The Increasing Importance of International Patent Issues

From May 2005 to March 2008 I had the privilege of serving as the U.S. Coordinator for International Intellectual Property (IP) Enforcement. We were tasked by Congress and the President to coordinate and leverage the resources of the U.S. Government to protect American IP at home and abroad. This effort included a number of steps designed to recognize the importance of international patent enforcement matters. We focused on three key elements: actively engaging our trading partners, promoting patent protection through trade policy and supporting U.S. businesses.

First, it was our experience that the direct and high-level engagement of the U.S. Government is critical to confronting challenges to the protection of innovation and IP globally. We led multiple interagency IP policy delegations to countries including China, India, Russia, and Mexico. These discussions underscored key concerns of the U.S. Government and focused on specific deficiencies that harmed U.S. companies as they sought patent protection. We also engaged extensively with partners such as the EU and Japan to coordinate efforts to promote global patent protection and launched efforts such as the U.S.-EU IP Working Group to institutionalize this collaboration. We coupled these efforts with engagement at the highest level, including inclusion of IP enforcement for the within the work plan of the G8 and the elevation of patent policy within key bilateral fora such as the Joint Committee on Commerce and Trade (JCCT) with China and the U.S.-China Strategic Economic Dialogue.

And, in an action that would become the touchstone for dialogue between the U.S. and China, former U.S. Ambassador Clark T. Randt, Jr. established the Annual Ambassador's IP Roundtable in Beijing. This event often included Cabinet-level participation from the U.S. and the presence of the Chinese Vice Premier.

Next, we established a framework that promoted broad principles of patent protection within our overall trade policy and trade agreements. The U.S. certainly has a tremendous amount of leverage as countries seek to expand their own access to the U.S. market, and 17 agreements negotiated with countries such as Australia, Jordan, Singapore, Peru, Korea, Chile, Panama, Colombia and CAFTA-DR all contain strong IP provisions including provisions that protect regulatory data, require patent linkage and make patent term restoration available to compensate for unwarranted delays in the marketing approval process. Today, ongoing negotiations to establish an ambitious Trans-Pacific Partnership (TPP) provide an important opportunity to continue this progression towards strong, effective global patent protection for U.S. businesses. TPP is being negotiated as if Trade Promotion Authority (TPA) were in place (which it unfortunately is not), and under this framework we should look to the Trade Act of 2002 which provided TPA until 2007 and which requires that agreements be modeled on existing U.S. law. This would argue for provisions such as a 5 year term of data exclusivity for small molecule drugs and 12 years of data exclusivity for biological drugs.

As part of our efforts, we also directly engaged a number of key trading partners to provide capacity-building programs designed to address weaknesses within their patent systems or enforcement procedures that negatively impact U.S. businesses. For example, a case referral mechanism was established allowing the U.S. Government to refer problems of patent enforcement directly to Chinese officials, the United States Patent and Trademark Office (USPTO) conducted numerous technical exchanges with major patent offices to increase their capacity and quality, a Patent Prosecution Highway was established to allow information sharing between certain patent offices, and experts from the Department of Justice helped train Indian judges to more effectively adjudicate IP infringement cases.

Finally, it was (and remains) critical for the U.S. Government to provide guidance and support for IP-intensive U.S. companies competing globally. In an environment of limited resources and competing priorities, there are smart and effective ways to assist U.S. companies by providing information and best-practices and also through direct intervention. In my opinion, the U.S. Government should have no reluctance to provide whatever support it can to assure U.S. companies compete on a level playing field as they seek to patent and commercialize their products in key markets. We will always

adhere to market-based principles and free trade, but the U.S. Government should not shy away from providing support and direct engagement when necessary. Here are some examples:

- The USPTO's Overseas Intellectual Property Rights Attaché program launched in 2006 has placed IP experts in seven countries including China, India, Brazil, India, Egypt, Thailand and Mexico. This program provides invaluable support to U.S. companies which have questions about important markets and/or face specific problems. U.S. IP attaches have engaged with hundreds of companies and interact daily with foreign IP officials to seek improvements and to advocate on behalf of U.S. companies.
- Nearly 20 Country IPR Toolkits were designed to provide U.S. companies (particularly small and medium-sized enterprises) expert guidance on patent policies and enforcement procedures in key global markets.
- In 2008, Secretary of Homeland Security Michael Chertoff and Secretary of Commerce Carlos Gutierrez joined with multiple federal agencies and business leaders to open an expansive Intellectual Property Rights Coordination Center. The IPR Center has become a critical resource for U.S. companies to engage directly with policy and enforcement agencies to address specific matters that impact their ability to protect their intellectual property.
- Using high-level bilateral engagement to pursue action on behalf of U.S. companies is a critically important role for the U.S. Government. In countries where decisions regarding issues such as patent exclusions, compulsory licenses and patentability are being made for political reasons it is appropriate and important for the U.S. Government to voice its concern and seek to counteract this activity. These practices often violate the letter and spirit of international trade law and our trade agreements and they will proliferate if not addressed in a serious manner. The U.S. Government should also seek out like-minded countries and remain very engaged and active within the World Trade Organization and the World Intellectual Property Organization, where efforts are underway to roll back existing patent protections.

II. Adequate and Effective Global Patent Protection is a Matter of U.S. Competitiveness

As efforts such as those outlined above have developed and grown, their importance has also increased dramatically. I would argue there are several key reasons for this.

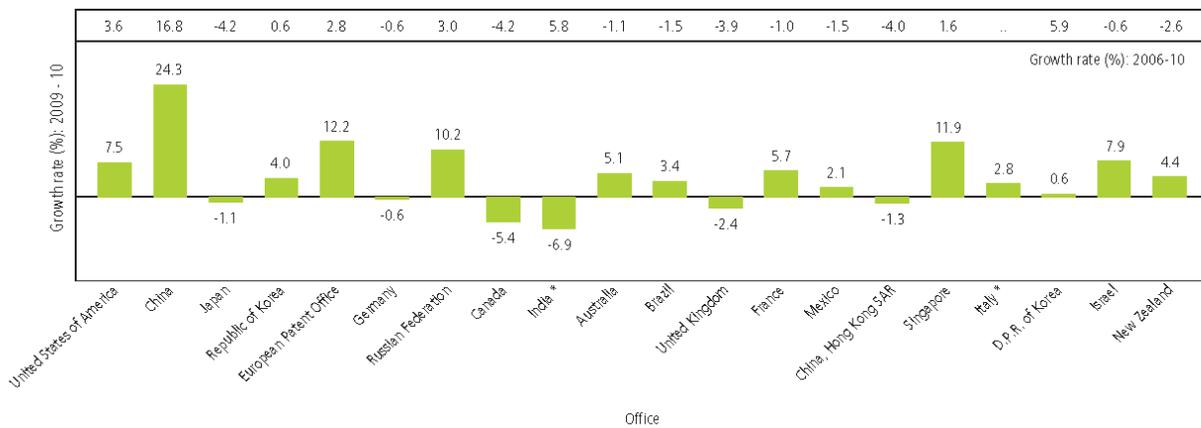
First and directly related to the work of this Committee, is the passage of the Leahy-Smith America Invents Act (AIA). The AIA represents a major achievement in strengthening and modernizing U.S. patent law and making it the global standard for quality and efficiency. Congress, working with the U.S. patent community and the USPTO, has made a number of critical improvements to our patent system that will unleash American innovation by improving patent quality, supporting U.S. manufacturing, providing more certainty for patent owners, and, very importantly, ensuring adequate funding for the USPTO. And under the leadership of USPTO Director Kappos we are witnessing the methodical and thoughtful implementation of the AIA. Unfortunately, many of our biggest competitors are going, either advertently or inadvertently, in the exact opposite direction. The patent backlog in Brazil is as long as 10 years, and when a patent is finally granted, Brazil provides wide exemptions for patent infringement that can make the patent nearly impossible to enforce. India's regional patent system can create tremendous problems with U.S. companies reporting that they have filed in separate regional patent offices and gotten opposite results. Thailand's regulatory authorities fail to even check if a valid patent exists when providing marketing approval for generic pharmaceuticals still under patent. And China is aggressively using its patent system to promote "indigenous innovation" and undercut U.S. innovators.

This disconnect, with the U.S. setting the global standard while other countries seek competitive advantages by racing to the bottom, is certainly not a new competitive dynamic for the U.S., but seeing it play out in terms of global patent policy is something policy makers need to be aware of and prepared to address.

Second, exacerbating this problem is the fact that we are seeing a dramatic increase in international patent filing, meaning that U.S. companies' exposure to an uneven playing field in terms of patent protection is growing exponentially. As depicted by the following chart from WIPO, the growth in patent applications in China, India and

Brazil from 2006-2010 was 7% a year. While the growth in patent applications in the U.S., EU and Japan over the same period was 0.7%. So, as the annual growth in applications to patent offices in the three historically largest offices has essentially leveled off in recent years, it is growing significantly in offices that have huge backlogs, major quality concerns and policies that undercut the overall value and enforceability of patents when granted.

Figure A.2.3.2. Growth rate of patent applications at the top 20 offices, 2010



Note: *Growth rates are calculated for 2008-2009 and 2006-2009. D.P.R. of Korea = Democratic People's Republic of Korea.
Source: WIPO Statistics Database, October 2011

Moreover, these countries are frequently seeking to export their policies through international fora such as the World Trade Organization, World Intellectual Property Organization, UN Framework Convention on Climate Change, World Health Organization and other bodies. For example, at the WIPO Standing Committee on Patents, Brazil has proposed that a manual be developed to instruct countries on how they can limit and weaken patent protections.

Third, and perhaps most importantly, the challenges and threats to global patent protection affect our most competitive and innovative companies and industries. As was reported by the Obama Administration in its March 2012 report “Intellectual Property and the U.S. Economy: Industries in Focus,” the 26 patent-intensive industries in the U.S. support 3.9 million jobs. These patent-intensive jobs are nearly all in the manufacturing sector, so for those who seek to promote a competitive U.S. manufacturing base, the ability to ensure strong global patent protection must be a high priority. Furthermore, this same report finds that jobs in patent-intensive industries pay on average 42% higher than those in non patent-intensive industries.

Not surprisingly, the U.S. patent-intensive industries also drive U.S. exports. Our innovative products lead the world and span multiple categories including health care, advanced manufacturing, chemicals, energy, transportation, software, information technology and others. These are areas where the U.S. must seek to increase its competitive advantage through innovation and global commercialization. This can only be accomplished when coupled with a policy approach that promotes strong patent protection.

Countries that undercut American innovation through overt practices such as compulsory licenses, patent exclusions, lack of data exclusivity, patent subsidies and others or through less obvious features such as lengthy application backlogs, weak judicial enforcement, pre-grant opposition or indigenous innovation policies are mounting a direct threat to U.S. competitiveness.

We should consider the ability of U.S. companies to gain effective global patent protection an issue of core American competitiveness in the same way we are attempting to improve our tax code, regulatory policy, education system, R&D portfolio and other elements critical to our economic growth.

III. Issues and Countries of Specific Concern

So, where does the rubber meet the road and what specific challenges do U.S. companies face internationally?

It is difficult to clearly articulate and categorize the myriad concerns facing U.S. companies, but in simple terms they can be seen in two broad areas: those that appear to be in direct violation of international agreements such as the WTO TRIPS Agreement and/or U.S. Free Trade Agreements, and those that are more process based and may not explicitly violate trading rules, but still undercut patent quality and strength of enforcement – we could call these “compliant non-compliance.”

The first category of direct violations is long and the problems have remained largely unchanged for years.

Exclusions, Restrictions, or “Flexibilities” on Patentability: WTO members are required to make patents available in all fields of technology, but a number of countries restrict patentability on a number of unrelated factors purely for competitive reasons.

For example, China requires filing an invention “made in China” prior to filing in another patent office. This is tremendously problematic for foreign applicants in what is now the world’s largest patent office. If applicants file first in China how does this affect their standing at the USPTO? This policy has nothing to do with the strength and quality of the patent process in China but is designed to force innovators to manufacture in China while likely putting their IP at risk.

India and Brazil do not allow patents for secondary claims for novel uses. This is particularly harmful for health care companies which often adjust and improve products to serve unique and underserved communities.

Provisions like these are all inconsistent with Article 27 of the TRIPS Agreement which stipulates that patents must be made available to “any inventions ... in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”

Another glaring example of patent exclusion is the fact that India excludes software patents as a whole except when combined with novel hardware. This does allow U.S. software companies to seek a limited level of patent protection in the important Indian market, but even this came under pressure recently when India considered eliminating all forms of patent protection for software in 2010. The U.S. Government, with notable leadership from the USPTO’s IP attaché program in India, filed comments with the Indian government and helped preserve the status quo, which is well below the standard of patent protection for software offered in the U.S. and the EU, but clearly better than the alternative proposed by India.

In the context of breakthrough U.S. innovations in clean technology, we have seen a major push from countries including China, India, Bolivia and Venezuela for a range in “flexibilities” in global patent rules under the false claim that patent protections hinder the flow of important energy-related technologies. This would include broad exceptions to patentability or possibly compulsory licensing ability for “essential” technologies. However, it has become exceedingly clear that proposals such as these are short-sighted attempts to expropriate U.S. innovation and they do not accurately capture the realities behind the flow of global innovation.

A study released by the Brookings Institution in November 2009 notes that, while, “research on the empirical effects of property rights on technology transfer, particularly to developing nations is murky ... strong IPR protection is an important catalyst for encouraging innovation in developing countries, and actually helps promote the sharing of technology as consistent and predictable legislative processes protect foreign direct investment and further joint ventures and international collaboration.”

Two additional reports also published in 2009 from the U.S. and the EU clearly conclude that intellectual property rights are neither a barrier to innovation, nor do they hinder the diffusion of clean energy technologies to emerging and developing economies. These reports, from the U.S. International Trade Commission (ITC) and the EU Directorate General for Trade (DG Trade) actually go further, and conclude, that, in the words of the ITC, “patents are facilitating, not stifling innovation.”

The EU’s report makes the case even more clearly and at length, “IPR protection is not the main barrier preventing the transfer of environmental technologies to developing countries. A large number of relevant technologies are not patented in low-income developing countries, and in emerging market economies a significant number is patented by local companies.” It goes on to say that, “there is a serious risk that a broad use of compulsory licensing (or other measures weakening IP rights) would constitute a disincentive for companies engaged in that sector, which might reduce their investment in such technologies. This would clearly be detrimental in the long term.”

Calls for weakening patent protections for clean technologies were specifically rejected during UNFCCC meetings in 2010, but a broad coalition of developing countries and anti-IP non-governmental organizations continues to pursue an active agenda to create an uneven playing field for U.S. clean tech innovators.

Data Exclusivity: Article 39.3 of the TRIPS Agreement provides for the protection of undisclosed data that is required in order to grant marketing approval to pharmaceutical, agrichemical or biotechnology products. This framework is important in order to protect the significant investment and IP that is required to support marketing authorization and demonstrate that products are safe and effective. This is an independent intellectual property right and while it should be linked to the underlying patent(s) which it supports, it is appropriately protected as it requires

significant additional scientific discovery, cost and time to demonstrate the safety and efficacy of complex new products.

An appropriate and enforceable period of data exclusivity ensures that innovators can effectively recover the massive investment necessary to create and market new products. It does nothing to prohibit generic manufacturers from entering the market, it merely requires that they do their own, independent tests to demonstrate that their product meets the safety and efficacy requirements of the regulatory agency.

The standard in U.S. law is 5 years of data exclusivity for small molecule medicines and 12 years for biological products. This sets the baseline for our existing Free Trade Agreements, and should be the model for any future U.S. trade agreements. However a number of countries such as Chile, Brazil, India, Russia, Argentina and others fail to provide effective protection for the proprietary data provided as part of the regulatory approval process in their country.

Compulsory Licensing: Of major concern to many U.S. innovators is the threat of countries issuing compulsory licenses for their products, essentially breaking the patent and allowing their competitors to manufacture and market a product in that country. This is a direct threat to the integrity and predictability of any patent system. If, often after up to 8-10 years, a valid patent can simply be brushed aside by a national government for reasons that often do not meet the narrowly-crafted framework which allows for compulsory licensing, U.S. innovators can have very little confidence in the major investments they make to bring their products to many emerging markets.

It is true that compulsory licensing is a tenet of WTO trading principles and was clarified to address emergency situations as part of the Doha Development round of negotiations in 2000. However, the framework around the issuance of compulsory licenses remains ambiguous and there are few limitations on countries that threaten to break patents under a compulsory license as a negotiating tactic with innovator companies. In addition, there is no clear floor for compensation offered to innovator companies whose patents are issued under a compulsory license. When the government of Thailand issued compulsory licenses around a number of drugs designed to address AIDS and heart disease in 2006 the level of compensation provided

to the innovator companies that held the patents was 0.5% of the sale of the generic versions that were promoted by the government.

What is fairly clear within the context of rules for compulsory licenses is that they are designed to be issued to address “emergency” situations in countries where efforts to legitimately license products have been exhausted. In reality this is rarely the case. Brazil’s model of threatening compulsory licenses as a negotiating tactic with pharmaceutical companies is well known and is an area where the U.S. Government has frequently intervened to dissuade the Brazilians from using this tactic. An ironic twist to Brazil’s aggressive posture in promoting the use of compulsory licenses was highlighted in their own statements to the WIPO Standing Committee on Patents in 2010 when they complained that it took almost two years for their pharmaceutical industry to develop and produce a drug under compulsory license because the information necessary was not “sufficiently revealed to allow its production as promptly as desired.” Basically, by issuing a compulsory license they made it impossible to develop a sensible commercial relationship with the innovator company that probably would have brought a higher quality product to the market sooner in Brazil.

In a recent case that has garnered significant attention, India has for the first time issued a compulsory license related to a treatment for liver and kidney cancer produced by Bayer. While Bayer is a German-based firm, its U.S. subsidiary held the patent for the product in India. This case is noteworthy for a number of reasons and places a challenge before the U.S. government to contain the spread of similar actions based on India’s decision.

Exemptions from Infringement: Similar to provisions that specifically exclude categories of technology from patentability, several countries have established rules that explicitly shield patent infringers from any legal recourse. Brazil is again noteworthy in this regard as it has put in place several excessive exemptions to patent infringement. For example, a very wide and vague provision allows for private, non-commercial use of patented technologies that does not “result in prejudice to owner’s economic interests.” Experimental use related to research is also exempted, as is using patents as a source of new products. Pharmacies in Brazil can also use patented medicines for “individual cases” with no real definition of what that means.

It is of course, important to note, that limited exceptions can be made by countries provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner. However, a wide swath of exemptions such as those present in Brazil can conspire to create significant uncertainty with patent owners and undermine the important premise of allowing patent owners to reasonably exploit the rights that come with the granting of a patent.

Patent subsidies: The Chinese government subsidizes the development of domestic technologies by providing direct financial support for Chinese companies to file foreign patent applications. China is seeking to expand this program dramatically and hopes to generate 2 million patent filings a year by 2015.

“Compliant Non-compliance”

Beyond specific practices that often amount to direct violations of WTO rules or individual Free Trade Agreements, we also see instances where the laws countries may have on the books appear to be satisfactory and/or not specifically prohibited, but the situation on the ground for U.S. companies is still extremely unbalanced based on what amounts to small legal hooks that weaken patent enforcement. These practices take a variety of forms and are often part of larger national initiatives.

Indigenous Innovation: Under the framework of promoting Indigenous Innovation, China is discriminating against foreign competitors by limiting the ability of non-Chinese IP owners to access the Chinese market. *Indigenous Innovation Product Accreditation* systems proposed in China would impose onerous and discriminatory requirements on companies seeking to sell to the Chinese government and state-owned enterprises. These policies pose a significant threat to U.S. industries ranging from software to manufacturing. The U.S. Government and industry have taken a hard-line on these proposals and the Chinese agreed to limit them at the 2010 JCCT meeting, but the situation on the ground appears to have not changed sufficiently.

Patent Office Weakness or Inconsistency: Even if countries appear to have patent laws that may be adequate, it is often the case that the patent offices in those countries are extremely over-burdened and under-staffed. It commonly takes 8-10 years to get a patent approved in Brazil and with 4 co-equal, but not well-coordinated regional patent

offices in India, it is not unheard of to get opposite outcomes for similar applications filed in different offices.

This exacerbates the overall ability of patent owners to ultimately protect their innovations when patent quality is poor and multiple challenges can be mounted to the validity of a patent, often due to weak processes in the national patent office. This is an area where the experience and expertise of the U.S. can be a huge asset. The USPTO has been training and collaborating with patent offices in developing countries for years, and with the AIA as the global model for patent quality and efficiency, we should look to redouble these efforts.

Pre-grant opposition: Countries such as India, Australia, New Zealand, Vietnam and others have a system that allows third parties to formally oppose patent applications as soon as they are published by the patent office. This practice has led to obvious abuse as competitors and others seeking to create barriers for U.S. companies can delay and confuse the patent application process by overwhelming examiners with information which is not relevant to the process that should exist between the applicant and the patent office. Opening the patent application process to third parties exposes it to harmful and unnecessary delays.

Weak Judicial Enforcement: Just as patent offices in many emerging markets are struggling to modernize and meet the demands of an explosion of complex applications, the courts in those countries are struggling to handle complex cases of patent enforcement. Courts in India have just begun to handle patent cases and the standards for interpreting patent claims, enforcing injunctions and other matters are still in their infancy. The default for many U.S. companies seeking to enforce their patents in court is an exceedingly long process that rarely results in any type of protection.

Making matters worse, in China, the Supreme Peoples' Court has urged lower courts not to issue preliminary injunctions for "complicated technologies" such as biotechnology. And in China, is it common for senior party officials to personally attend major patent cases adding pressure on judges when the interests of the state are at stake against foreign companies.

This is an area where the U.S. has focused over the years and efforts such as those led by Chief Judge Randall Rader of the U.S. Court of Appeals for the Federal Circuit have made a tremendous difference. Judge Rader has traveled frequently to China and other countries promoting judicial independence and specialization for complex patent cases.

Patent Term Adjustment: The WTO TRIPS Agreement requires a patent term that must be at least 20 years from the date of patent application. Because the regulatory approval process is often very long, most developed economies have instituted procedures whereby patent owners can seek an extended period of patent protection to partially compensate for exceedingly long approval processes that can significantly erode the effective life of the patent. This type of balance allows patent owners to have the time and market exclusivity which is typically necessary to justify the huge underlying investment made to develop and bring a product to the market. The reality is that most major emerging markets do not offer any form of patent term extension, these include China, Brazil, India, Chile (despite it being a requirement of the U.S.-Chile FTA), Canada, Argentina, New Zealand, South Africa and others.

Conclusion

Mr. Chairman, the challenges and opportunities for U.S. companies in global markets are both extraordinary. This committee has raised an important issue that impacts countless U.S. businesses of all sizes and is at the core of our overall global competitiveness. It is very clear that U.S. companies face tremendous complexity and difficulty as they seek out global markets. But as the most competitive and innovative nation in the world, there are an even greater number of opportunities.

Congress is presented with a tremendous opportunity to promote a strong global environment for patent protection based on its work to modernize and strengthen our system in the U.S. U.S. companies do not just seek to protect their innovations at the USPTO and then stop, they move on to countless other global markets to bring their innovations and breakthroughs to the millions of consumers outside our borders. We should look to support these efforts by promoting the strong patent laws and practices we have developed in the U.S. through the America Invents Act and its continued implementation in markets around the world.

I truly appreciate the opportunity to participate in this hearing and look forward to any chance to support the work of the Committee in the future.