GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

By electronic transmission

February 11, 2008

Jennifer Choe Groves
Director for Intellectual Property and Innovation and Chair of the Special 301 Committee
Office of the United States Trade Representative
Washington, D.C.
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Re: Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment, 73 Fed. Reg. 11 (January 16, 2008)

Dear Ms. Groves,

The Generic Pharmaceutical Association (GPhA) appreciates this opportunity to provide input into USTR's consideration of the identification and designation of countries for inclusion in the *2008 Special 301 Report*.

GPhA represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry.

GPhA members manufacture the vast majority of all affordable pharmaceuticals dispensed in the United States. Our products are used in more than one billion prescriptions every year. Generics accounted for 63% of all prescriptions dispensed in the United States in 2006, but because a generic medicine can cost 30% to 80% less than its equivalent brand-name drug, generics account for only 20 cents of every dollar spent on prescription drugs.

The generic pharmaceutical industry is a source of robust competition in the United States that offers real and growing benefits to American consumers much in need of affordable medicines. We were pleased to see the section on "Supporting Pharmaceutical Innovation" in the *2007 Special 301 Report* give credit for the first time to U.S. reliance "on a strong generic pharmaceutical industry to increase competitive pressure to lower drug prices." In our view, the successes of the U.S. healthcare system and the U.S. pharmaceutical industry writ large may be attributed to the prudent balance in the structure of the U.S. pharmaceutical market that encourages true innovation while also facilitating access to affordable generic medicines.

The May 10 bipartisan compromise on trade is an important step forward in ensuring that U.S. free trade agreements reflect the balance struck in U.S. law between fostering drug

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innovation and ensuring access to affordable medicines. It modified some key provisions that had diverged from U.S. law in earlier agreements that could restrict the public's timely access to medicine at home and abroad. This is particularly true with respect to the two most common pharmaceutical IPR concerns raised in the *2007 Special 301 Report*, "inadequate protection against unfair commercial use for data generated to obtain marketing approval" and "insufficient coordination between health and patent authorities to prevent the issuance of marketing approvals for patent-infringing pharmaceutical products." USTR cited these concerns ubiquitously in the 2007 report and used the same general language to cover a wide range of country practices. We urge you in this year's report to provide greater specificity when USTR cites IPR protection as inadequate in these areas, and to be attune to changed expectations regarding foreign country policies and practices, as expressed in the new provisions of the May 10 bipartisan compromise.

Another new development in the *2007 Special 301 Report* was the attention given to trade in counterfeit pharmaceuticals. We applaud this focus. The safety of foreign products has risen to the top of U.S. consumer concerns during the past year, and given the risks to human health and safety, nowhere is it more important to address fraudulent behavior than in pharmaceutical products.

The fact is, FDA-approved prescription drug manufacturers -- brand and generic -- operate in a highly regulated environment to ensure the safety and efficacy of medicines taken by million of Americans every day. Congress and the FDA have promulgated strict rules governing the development, manufacture, approval, packaging, marketing and post-marketing surveillance of FDA-approved prescription drugs. As a result of FDA regulations, the brand and generic FDA-approved pharmaceutical supply chain is perhaps the most rigorously tested process in product manufacturing in the world.

While the generic industry does not face the same counterfeiting problems that exist in the brand sector where price and demand are high, we still get "side-swiped" when consumers confuse high quality generics with unregulated, counterfeit or inferior drugs.[1] Today, there are thousands of generic drugs available and all are manufactured and inspected under the same strict quality guidelines as a brand. It is critical that the domestic pharmaceutical distribution system be strengthened to address existing weaknesses in the oversight of the unapproved and unregulated drug market to protect consumers from substandard and potentially harmful

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[1] In this regard, we must take exception to the commentary in *PhRMA's Special 301 Submission* last year which characterized innovative products and their generic counterparts as "…'like products' for WTO purposes, *even though the innovative product is of superior quality....*" (p. 105) GPhA completely agrees that innovative products and their generic counterparts are "like products" for WTO purposes, but finds it reprehensible for PhRMA to claim that the innovative product is superior. According to the U.S. Food and Drug Administration, "[A] generic drug is identical or bioequivalent to a brand-name drug in dosage form, safety, strength, route of administration, *quality*, performance characteristics and intended use." [emphases added] With a generic, you get the same medicine as the brand, with the same quality and same result, but at a much lower cost.

medicines, and to prevent counterfeit products from entering the U.S. drug supply. We stand ready to work with you to address this growing problem.

Finally, as this is our first submission to the Special 301 process, we would like to focus our comments this year on just one country that is of particular concern to GPhA -- Israel. Israel is an important supplier of generic drugs to the United States through such companies as Teva, Perrigo and Dexxon. Israel was first elevated to the Priority Watch List in the *2005 Special 301 Report* and has remained there since, reflecting in large part concerns that have been raised by PhRMA each year. PhRMA's 2007 submission starkly asserted that "the revisions in Israel's pharmaceutical IP laws, that took place in the past seven years, have resulted in a sharp deterioration in the level of protection provided to U.S.-based innovators operating in Israel." [emphasis added]

We strongly disagree. Israel has taken significant steps to meet its international IPR obligations, and we believe that it is time for USTR to acknowledge these improvements and remove Israel from the 2008 report.

To be clear, PhRMA cites four areas as the focus of its concern.[2] Let's examine the record.

The first complaint is the circumvention of the principle of national territoriality vis-à-vis "the so-called Israeli Linkage Mechanism", which relates the period of IPR protection for patent term extension and data exclusivity to the earliest date of product approval in any one of the "recognized countries." This charge of circumvention is mumbo jumbo. The territoriality principle in international intellectual property law "…means that it is the law of the country where protection ... is sought which determines the condition of that protection."[3] This territoriality principle has nothing to do with prohibiting Country A from referencing Country B's terms or conditions of IPR protection in determining what protection it will apply under its own national IPR laws. For example, the NAFTA agreement to which the United States is a party provides for a linkage mechanism for data exclusivity: "Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on." (Article 1711(7))[4] And we are quite certain that PhRMA would not complain that the principle of territoriality is being circumvented by Section 17 (c) of the Israeli Patent Law, which lets an applicant rely on a corresponding patent that has been issued by the U.S. Patent and Trademark Office to obtain a patent in Israel without substantial examination merely by conforming its claims in certain areas.

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[2] PhRMA's submission actually says "five" areas, but it only lists four.

[3] Court of Justice of the European Communities, June 22, 1994, case C9/93 (Ideal-Standard), GRUR Int. 1994/7, 614.

[4] See also the so-called "concurrent period" provided in the May 10 bipartisan compromise with respect to data exclusivity, discussed in the text below.

The second complaint is that a 2005 amendment to the Patents Act "considerably shortens the patent extension term and would possibly nullify it completely." This is in part a reference to the Linkage Mechanism (above), which can curtail patent term extensions to the shortest term allowed by one of the following countries: the United States, Canada, the EU-15, Norway, Switzerland, Iceland, Japan, Australia and New Zealand. Actually this condition was already part of the legislation in 1998 that first granted patent term extension in Israel for up to an additional five years, when the reference countries did not comprise a finite list of 21 developed countries, but rather included all Bolar countries. At the time, this legislation was welcomed by the United States and PhRMA because Israel has no international obligation to provide even a one-day extension. The 2005 law was necessitated to rectify an ex-parte decision of the Israeli Patent and Trademark Office which effectively nullified the intent of the Israeli Knesset (Parliament) in legislating the 1998 law. The continuation of the "Linkage Mechanism" in the 2005 amendment did not result in any reduction in the patent extension term Israel provided versus what had been provided in 1998.

Rather the 2005 amendment clarified the implementation of the 1998 law and added a new feature to condition patent term extension on the granting of a corresponding extension in the United States or in one of the EU-15 (if the product is registered there). While this new condition may not have been welcomed, it hardly amounts to piracy.[5] By way of comparison, many countries -- including some developed countries -- do not provide for any patent term extension. For example, the total lack of patent extension was an important factor cited by PhRMA in seeking a Priority Watch List designation for New Zealand last year, yet New Zealand is not even mentioned in the *2007 Special 301 Report*. It should not escape notice that in the entire *2007 Special 301 Report*, Israel is the only country USTR cites for problems relating to patent term extension.

The third complaint is inadequate protection of regulatory registration data (data exclusivity). Far from representing a sharp deterioration in protection over the past seven years, in March 2005, Israel approved legislation that provided data exclusivity in Israel for the first time. PhRMA and USTR dismiss this protection as inadequate because it provides for 5 years of data exclusivity (the term of protection provided in the United States) from the date of registration in Israel, or 5.5 years from the date of approval for use in a "recognized country." PhRMA claims this yields an effective term of only 3.5 years, although it acknowledges that a draft guideline would make the effective term 4.5 years. In the meantime, the said guideline has been accepted and approved. Moreover, the Israeli Ministry of Health ("MOH") has stated its goal to further shorten the duration of the registration process to six months, as was the case only a few years ago.

Surely this temporary situation at the MOH is not the basis for a Priority Watch List designation, for while there is much debate about what kind of protection Article 39.3 of TRIPs actually requires, even those countries that maintain it requires a period of data exclusivity (such as

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[5] Moreover, requiring the patent term extension in Israel to be extended beyond the expiration of the extension of the corresponding patent in the United States would have a significant negative impact on both the U.S. generic market and the end consumer. Such an extended term of protection would prevent the U.S. generic manufacturers from sourcing their active pharmaceutical ingredient (API) from Israel (and other countries).

the United States) agree that the obligation is silent on the length of the period required.[6] Moreover, the Government of Israel says the rationale for this linkage mechanism is to induce prompt registration of new drugs in Israel. As such, it can be seen as compatible with the provisions in the May 10 compromise on data exclusivity, which call for 5 years of data exclusivity as a general rule, but include incentives for innovative companies to promptly seek marketing approval in our free trade partners and for our free trade partners to process the application quickly by providing for a so-called "concurrent period" which would provide for less than the full five years of data exclusivity protection afforded in the United States.[7]

It is possible that the larger concern was the assertion by PhRMA that the MOH could rely on the registration data to approve the export of generic products to other markets, a "sub-standard type of protection [that] ensures that local generic companies would enjoy an unfair competitive advantage over their U.S. and other generic competitors."[8] In truth, no reliance is made on the registration data of the brand-name manufacturer in approving the export of generic drugs. Quite the contrary, the MOH's permit for export focuses on maintaining GMP (good manufacturing practices) standards. This was explained before publication of the *2007 Special 301 Report* in which USTR noted (rather grudgingly), "Information provided by Israel regarding steps it has taken to preclude reliance on data generated to obtain marketing approval for exports is a positive step towards addressing the United States' concerns on this issue."[9] We note further that exportation during the period of data exclusivity is expressly allowed and encouraged both under U.S. law and FDA regulations.

The fourth complaint is substantial delays in the publication of patent applications and the grant of patents (particularly the system of pre-grant patent opposition). Again, far from a deteriorating situation, Israel has been taking steps to address these concerns. One problem has been the routine delay of several months in the monthly publication of the *Israel Patent Office Journal*, raising confusion as to whether an Israel patent was prior art to a patent application or not. This problem was corrected last February by termination of publication of the *Journal* in hard copy, replaced by the timely availability of *Israel Patents* in PDF format. Another problem cited by PhRMA is that unlike most industrialized countries that publish patent applications 18 months after the first filing date, the Israeli Patent Authority only publishes allowed patent applications for opposition purposes once the examination process is complete. In June 2007, a private bill to amend the Israel Patent Law was proposed that would adopt the 18 months that is common

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[6] Even PhRMA agrees on this point. In calling for Argentina to be designated to the Priority Watch List, PhRMA says in its 2007 submission, "Argentina does not provide for protection of undisclosed test and other data in a manner that is consistent with its obligations under TRIPS Article 39.3, especially the requirement to protect such data against unfair commercial use, i.e., reliance by Argentine officials on the data submitted by one person to approve requests by competitors to market similar products *for a specified period* following the approval of the product associated with the submitted data." [emphasis added] (p. 134)

[7] In fact, this "concurrent period" is defined as a five year period that begins from when the drug was first approved in the United States, not from when it was registered in our free trade partner, and is exactly the same concept.

[8] Submission by PhRMA to the *2007 Special 301 Report*, pg. 174

[9] *2007 Special 301 Report*, USTR, pg. 26.

elsewhere. The Israeli Ministry of Justice is also considering a similar amendment. In the meantime, this timing difference is not a significant obstacle to effective patent protection.[10]

Improvements have also been made to the open ended pre-grant opposition proceedings applicable under Israeli law that can lead to long examination periods. Under reforms that began in 2006, litigators have been fined for unacceptably long delays, baseless requests for extensions, and groundless opposition proceedings. These reforms will benefit all parties, as inefficiencies and potential abuse of the system operate in both directions, affecting both innovators filing for a patent and generic producers contesting patent validity. Israel also is not the only country that still utilizes a pre-grant opposition system, and PhRMA is not presenting the entire picture when it says that "The legal situation in Israel is diametrically opposed to the standard legal situation worldwide, least of all OECD countries. In most of the developed countries, any opposition proceedings are conducted post registration and it is not possible to block grant of the patent." Australia and New Zealand, both OECD members, use similar opposition procedures, and neither of these countries is included in any of the *2007 Special 301 Report's* Watch lists.

Finally, it deserves mention that the alleged damages related to Israeli acts, policies and practices are far from those with "the greatest adverse impact (actual or potential.)"[11] Of the 23 countries that PhRMA both recommended be included in the *2007 Special 301 Report* and for which it provided damage calculations with respect to "two broad forms of IPR infringement -- data exclusivity and patent protection", Israel had the lowest absolute dollar value of alleged damages for data protection, the second lowest for patent protection, and the lowest total damages. Even when these damages are adjusted for market size by considering them as a percent of sales, Israel still comes out in the lowest quartile.

The inescapable conclusion is that Israel has taken significant steps in the last few years to come into compliance with its international IPR obligations, and provides TRIPs-plus protections in key areas that exceed the current level of protection by many other countries on

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[10] Noting that most Israeli applications are filed abroad anyway, Dr. Michael Factor, an Israeli patent attorney, suggests a simple work-around. "Until the Law changes, we believe that on balance, it is preferable to obtain a priority date by first filing in Israel. The filing fee is 1092 NIS, which is a mere $250, and the application can be abandoned and thus never published, just like a U.S. Provisional Application. Furthermore, under certain circumstance, additional material can be added to pending Israeli applications. It will be noted, however, that once an Israel application is used as a Priority Document for the subsequent filing of a regular U.S. application or a PCT application under the Paris Convention, it will publish 18 months after filing, in the file wrapper of the U.S. application or the PCT, and is available from the USPTO and WIPO websites respectively." *The IP Factor*, July 2, 2007 (http://blog.ipfactor.co.il/2007/07/02)

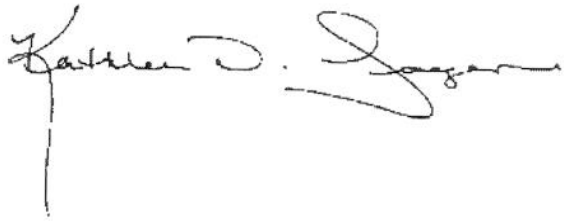
[11] The reference is to the statutory requirement of Section 182 of the Trade Act of 1974 (19 U.S.C. 2242) which requires USTR to identify those countries that deny adequate and effective protection for intellectual property rights or deny fair and equitable market access to U.S. persons who rely on intellectual property protection. Those countries that have the most onerous or egregious acts, policies, or practices, and whose acts, policies, or practices have the greatest adverse impact (actual or potential) on the relevant U.S. products are to be identified as Priority Foreign Countries (PFC). While USTR characterizes countries placed on the Priority Watch List (PWL) as those that are the focus of increased bilateral attention concerning problem areas, the undeniably similar terms -- Priority Foreign Country and Priority Watch List -- necessarily suggest that countries on the PWL are skating on thin ice and are at risk for being designated PFC.

the "Priority Watch List", the "Watch List", and indeed by some countries that are not mentioned in the report at all. Far from being unresponsive and presenting a deteriorating situation, Israel is affording U.S. pharmaceutical innovators an overall stronger and improving regime of IPR protections.

We respectfully suggest that it is time for the U.S. Government to acknowledge this progress by removing Israel from the *2008 Special 301 Report*.

Thank you for taking these views into consideration and we look forward to continuing our work with USTR to develop trade policies that are consistent with bringing competition into the pharmaceutical marketplace that results in lower consumer costs without stifling innovation.

Respectfully submitted,



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