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February 11, 2008
Ref: T/44/479

By E-Mail

Dear Ms. Groves,

Re: **Manufacturers Association of Israel—"Special 301 Report" Submission**

The Manufacturers Association of Israel (**"the MAoI"**) makes this submission to the United States Trade Representative (**"the USTR"**) in anticipation of the 2008 "Special 301 Report". As shall be fully explained in this submission, the MAoI reaffirms its position that Israel should be removed from the USTR's "301 Reports" altogether, including from any of its Watch Lists.

I. Preamble

The MAoI regrets that, despite previous submissions to the USTR, Israel nevertheless remained on the "Priority Watch List" (**"PWL"**) in the 2007 "Special 301 Report" (**"the 2007 report"**). As in the previous two "Special 301 Reports", the 2007 report focuses its complaints against Israel mainly on its level of IP protection for pharmaceuticals, *i.e.*, its Patent Term Extension (**"PTE"**) and Data Exclusivity (**"DE"**) laws. As was fully explained in the MAoI's previous submissions, the elevation of Israel in 2005 from the USTR's Watch List (**"**WL**"**) to the PWL was based upon an erroneous analysis of Israeli law, which may have resulted from misrepresentations made by the Pharmaceutical Research and Manufacturers of America (**"PhRMA"**) in submissions issued by PhRMA to the USTR.

The MAoI was encouraged to see that, in the 2007 report, the USTR acknowledged, albeit not absolutely, the clarifications made by the Israeli Government and the Israeli Ministry of Health (**"the MOH"**) in particular (as well as those made by the MAoI), regarding the fact that Israel's DE legislation does not facilitate reliance on the originators' dossiers for the export of generic drugs during the DE period. Regrettably, the rebuttal of PhRMA's baseless allegations in this important respect did not result in any improvement of Israel's designation on the WLs. It is inconceivable and

unfair that the USTR chooses to give no weight, in terms of the ranking, to a change of the factual basis with respect to an issue previously found to be important, in terms of forming its position on Israel's ranking[1].

The MAoI therefore urges the USTR to read, anew, its previous submissions and, having regard to the arguments raised in them—together with the said clarifications regarding the exportation of generic drugs during the DE period—to fairly provide adequate weight to them in its 2008 "Special 301" review process.

In this interim submission, the MAoI will focus on the following:

(i) the insufficient reasoning in the 2007 report for setting the goal of a higher level of intellectual property protection which the USTR expects of Israel;

(ii) the continuing and ongoing discrimination against Israel in the 2007 report; and

(iii) the non-transparency of the "special 301" review process.

Notwithstanding the above, it should be emphasised that if and when PhRMA's "Special 301 Report" Submission for 2008 is published, or made available to us, we shall, at such time, submit comments thereto, and also request the USTR to regard those comments as an integral part of this interim submission, as the USTR has kindly agreed to do in previous years.

II. The USTR unjustifiably sets a higher goal for Israel in terms of IP protection for pharmaceuticals

In the 2007 report, the USTR stated that:

> "the United States looks to Israel to provide a higher level of protection that reflects its status as a partner in the U.S.–Israel FTA and its objective of becoming a member of the OECD."

Clearly, the USTR acknowledges that the level of IP protection for pharmaceuticals in Israel neither amounts to a breach of its international obligations nor falls below established international standards (first and foremost—TRIPS). Setting aside for now the legitimacy of designating a country as a PWL country in such circumstances, the reasons provided by

1 *See* the section on Israel in the 2006 National Trade Estimate Report on Foreign Trade Barriers, on p. 334, as well as PhRMA's "Special 301 Report" Submissions for 2006-2007, both on p. 139.

the USTR, on the basis of which it expects Israel to increase its level of IP protection are, in and of themselves, without merit, in light of the following:

(a) *The U.S.–Israel FTA*

Israel's status as a party to the U.S.–Israel FTA (**"the FTA"**) by no means entails that Israel should provide a higher level of IP protection; if at all, it provides an indication that it is not required to do so. The relevant article of the FTA dealing with IP (Article 14), states that:

> "The Parties reaffirm their obligations under bilateral and multilateral agreements relating to intellectual property rights, including industrial property rights, in effect between the Parties".

On the one hand, it cannot be disputed that Israel is not in breach of Article 14 of the FTA, since:

(i) the USTR's demands of Israel are not based on its obligations under **any bilateral or multilateral agreements**; and

(ii) at the time of signature of the FTA or upon its entry into force (in 1985), no bilateral or multilateral agreements which could, even remotely, form a basis for such demands, were in existence. Thus, no such obligations—giving rise to the USTR's demand—were **"in effect between the Parties"**.

It should also be noted that the FTA was signed after the enactment of the Hatch-Waxman Act, which introduced PTE and DE into US law, but did not require Israel to follow that path and adopt similar measures in Israel's IP laws.

On the other hand, not only is Israel not in breach of the FTA, but it is arguable that the demand made by the USTR, and the sanctions taken against Israel by designating it a PWL country, amount to breach of the FTA by the US, since:

(1) the intent and spirit of the FTA, as its name connotes, is to promote **free** trade between the US and Israel. This is also explicitly provided for in the preamble to the FTA, where it states: "The Government of the United States of America and the Government of Israel … wishing to establish bilateral **free trade between the two nations** through the removal of trade barriers …". Any further amendment to Israel's IP legislation with respect to pharmaceuticals would delay the entry of Israeli-produced generics, particularly into the US market. Such measures would hinder competition of Israeli-manufactured pharmaceuticals with US innovative as well as generic drugs. Thus, the pressure imposed on Israel by the USTR to further

amend its IP laws, where any such further amendment would certainly **not** be based on Israel's obligations under bilateral or multilateral agreements, breaches, at least, the intent and spirit of the FTA; and

(2) Article 14 reflects the balance struck in the negotiations of the FTA. Raising the standard as the USTR does through its "Special 301 Report" unilaterally tilts the scales and seeks to change that balance. The undertaking of Israel, under Article 14, is obviously to honour its obligations under agreements "in effect between the Parties". But until a new agreement is negotiated, the US should also respect the FTA and the balance it reflects. Requiring Israel to adopt norms that go beyond bilateral or multilateral agreements and which are not specifically referred to in Article 14 of the FTA, constitutes a violation of the said Article.

(b) *Intellectual property protection in OECD member countries*

The other basis for the USTR's decision to hold Israel to a higher standard is "its objective of becoming a member of the OECD". That reasoning is untenable, since:

(i) the US openly supports Israel's efforts to become a member of the OECD. Congress itself has clearly spoken on the subject, in strong support of Israel. The USTR is turning Israel's objective against it, by alluding, or suggesting, in a formal public statement, *i.e.*, its "Special 301 Report", that Israel is not "up to the standard" in terms of IP protection, and not yet worthy of being allowed to join the OECD, for lack of satisfactory IP protection. Those insinuations are not only neither valid nor true, in and of themselves (as shall be detailed below), but they are not helpful and may undermine the joint Israel-US efforts regarding Israel's accession to the OECD; and

(ii) Israel's IP protection is not sub-standard, not even amongst OECD members.

OECD member countries do not share a uniform standard of IP protection, for pharmaceuticals or otherwise. In fact, no agreement exists amongst the OECD member countries expressly defining the required standard of IP protection, nor are there accepted guidelines on IP which may be relied upon by OECD member countries. The standards of IP protection in place in OECD member countries are variable. Thus, while the USTR's argument strongly implies that OECD member countries all provide higher IP protection for pharmaceuticals than Israel, the facts indicate that different levels of IP protection exist amongst the OECD member countries—some being higher than that provided by Israel, while others are lower.

For example, although the USTR strongly criticizes Israel with respect to the scope of its PTE and DE legislation, the fact remains that Israel provides for *both* PTE and DE while, for example:

- **Mexico**, an OECD member country, does not provide for any PTE whatsoever. Mexico also does not provide DE protection that meets the requirements of USTR either;

- **Canada** and **New-Zealand**, OECD member countries, do not provide for any PTE whatsoever;

- **Turkey**, yet another OECD member country, does not provide for any PTE whatsoever, and its DE term is limited (*inter alia*, the DE term is subject to the patent term); and

- **Korea**, an OECD member country, currently does not have express DE legislation in place and its *de facto* level of DE protection is questionable.

Israel, on the other hand—not yet an OECD member country—provides for PTE of up to 5 years, for so long as it is in effect in the developed reference countries, such as the USA. Israel also provides for up to 5.5 years of DE, provided the innovator is prompt in applying for registration in Israel. Nonetheless, while the USTR has not commented on total lack of PTE with respect to any other OECD member country, it made this issue a cornerstone of its decision on Israel.

Thus, the level of IP protection provided by Israel to innovative drugs is higher than that provided by some OECD member countries (and, of course, higher than that provided by most non-OECD member countries).

The attention of the USTR is also drawn to the fact that recently, senior officials of certain R&D-based companies, such as Baxter and Merck AG, publicly expressed their views on the matter of Israel's IP laws and specifically stated that they do not perceive Israel's IP laws to be problematic and, in fact, added that Israel has strong IP, and strong IP protection (translations into English of articles published in the Israeli press (in their original Hebrew) are attached hereto and marked **"A"** and **"B"**, respectively). This is yet another indication that the position presented to the USTR by PhRMA is without merit.

Finally, the roadmap for the accession of Israel to the OECD Convention (adopted by the Council at its 1163rd session on

30 November 2007)[2], made no reference to the issues raised by the USTR, *i.e.*, PTE and DE. This fact further demonstrates that the "OECD-level" argument, raised in the 2007 report as a basis for Israel's classification, lacks any merit.

III. The continuing and ongoing discrimination against Israel in the 2007 report

As noted in the preamble above, the USTR has, in the 2007 report, designated Israel on the PWL together with **China**, **Russia**, **Argentina**, **Chile**, **Egypt**, **India**, **Lebanon**, **Thailand**, **Turkey**, **Ukraine** and **Venezuela**. Clearly Israel does not belong in that "club", in terms of IP protection in general, and with respect to pharmaceuticals in particular, since:

- the vast majority of PWL countries do not provide for <u>any</u> PTE or DE whatsoever, while the remaining PWL countries provide less DE protection than Israel;

- the vast majority of countries which the USTR chose to designate <u>only on the WL</u>, do not provide for <u>any</u> PTE whatsoever. Many WL countries provide less DE protection than Israel, or no such protection whatsoever. Countries which provide less protection than Israel but are on the WL include, for example: Brazil, Mexico, Canada and Korea;

- even OECD member countries, which do not provide for <u>any</u> PTE whatsoever are, except for Turkey, nevertheless designated only on the WL. New Zealand, another OECD member, which does not provide any PTE, is not mentioned at all in the 2007 report. Turkey is indeed designated on the PWL, but that not only (or even mainly) due to issues related to IP protection for pharmaceuticals, and certainly not for reasons relating to PTE, but also—and, perhaps, most significantly—due to copyright enforcement issues; and

- Brazil, which does not provide for <u>any</u> PTE whatsoever, and also does not provide DE protection that meets the requirements of the USTR either, was nevertheless **<u>downgraded</u>** in the 2007 report from the PWL to WL status.

IV. The non-transparency of the "special 301" review process

The process by which the USTR carries out its comparison of the levels of IP protection accorded to pharmaceuticals in different countries, and thus its ranking of those countries on the 301 lists, lacks transparency. Despite argumentation describing its process as transparent, the USTR declined to disclose most of its documents on the subject, even in response to an application under the Freedom of Information Act, followed by an appeal to

2 Document C(2007)102/FINAL, accessible at http://oecd.gov.il/files2/Roadmap%20-%20Israel(1).pdf.

the FOIA Appeals Committee, both of which were filed by the MAoI in recent months. From the index that the USTR agreed to provide to the MAoI, there does not seem to be any post-deliberation document outlining the reasons for Israel's designation on the PWL in the last three "Special 301 Reports".

In bipartisan letters (attached hereto and marked **"C"** and **"D"**, respectively), members of the US Congress and Senate expressed their concern that the USTR's treatment of Israel impairs the trade relationship between the US and Israel, and that it is "ultimately detrimental to our relations with our most important ally in the Middle East". As may be discerned from those letters, the relevant members of the US Congress and Senate specifically requested that Israel be removed from the USTR's "Special 301 Report" altogether and advocated "a transparent and fair process", to ensure that the report "serves as a useful and balanced guide to intellectual property protection around the world".

Notwithstanding the above, the USTR has admitted that it has no clear formula or criterion on the basis of which it compares and rates various countries considered for the WL (*see*, in this regard, the document attached hereto and marked **"E"**, which was amongst the few documents disclosed pursuant to the MAoI's FOIA request referred to above).

The MAoI accordingly urges the USTR to develop and/or disclose clear and fair criteria that form the basis for its decision with regard to Israel's inclusion in the 2008 report.

V. Summary

As fully explained in the MAoI's previous submissions, the elevation of Israel in 2005 from the WL was based upon an erroneous analysis of Israeli law, which presumably resulted from misrepresentations contained in submissions issued by PhRMA to the USTR. In addition, and as demonstrated above, the reasons provided by the USTR in the 2007 report as to why it expects Israel to provide a higher level of intellectual property protection are without merit, both with respect to Israel's status as a party to the FTA, and with respect to the notion that OECD member countries, as such, provide higher IP protection for pharmaceuticals than Israel.

The truth of the matter is that Israel was clearly discriminated against not only in the 2007 report, but also in the 2006 and 2005 "Special 301 Reports", as demonstrated in previous submissions by the MAoI. The MAoI further believes that the non-transparency of the "Special 301" review process, and lack of clear criteria for the inclusion of Israel in the USTR's "Special 301 Reports" have contributed to and/or facilitated Israel's unfair and discriminating designation on the PWL in recent reports.

The USTR's unjustified approach may be detrimental to the entire Israeli pharmaceutical industry, which is an important constituent of Israel's growing economy. Moreover, it may lead to denial of access by the Israeli

public to important medicines, as illustrated in an official letter recently issued by the MOH (a translation of which is attached hereto and marked **"F"**). As may be gleaned from the letter, the Minister strongly opposes further amendment to the Israeli legislation, as this would be at the expense of patients, who would be denied access to medicine.

Accordingly, and as explained in this and previous submissions, Israel should be removed from any future "Special 301 Reports" altogether, and from any of its Watch Lists.

Kind regards,

Yours sincerely,

Tal Band, Adv.
S. Horowitz & Co.

(This document is being transmitted directly via the computer and therefore has not been signed manually by the author thereof)