AMBASSADOR
EXTRAORDINARY AND PLENIPOTENTIARY
PERMANENT REPRESENTATIVE

CIM would like comments on the issues raised in PR's letter, particularly on Paras 3/4 & 9, please

21.2.05
JS (CIM)

No. GEN/PMI/241/4/2005

February 1, 2005

Thank you for your very comprehensive telefax of 23 January in response to mine of 19 January 2005 regarding the recent Patent (Amendment) Ordinance. We shall take advantage of the useful information provided to counter any erroneous impression regarding the Ordinance, both within the IP community in Geneva and among others.

2. Whilst the specific clarifications contained in your letter address very important issues, I must share with you that I have a nagging feeling that the opposition to the Ordinance is unlikely to dissipate soon. Concerned groups everywhere, in India and abroad, would be watching anxiously to see how the legislation eventually pans out. Important as the international interest in our Patent Ordinance may be, it is even more important to focus on its possible feedback effect on the process of ratification of the Ordinance in Parliament. In order to anticipate any opposition, and thus be better equipped to counter criticism, I would like to submit the following on the clarifications contained in your letter.

3. You have mentioned that para 2(a)(iii) of the WTO General Council's decision of 30th August 2003 specifically talks about issue of a compulsory license by the *importing* country. Indeed, it does. But the Ordinance seems to have overlooked a crucial clause in 2(a)(iii) of that decision - which is what gave rise to one of the major concerns that prompted the New York Times editorial. Let me reproduce the sub-paragraph in its entirety.

"(a) the eligible importing Member(s) has made a notification to the Council for TRIPS, that:

(i) .....

(ii) .....

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision".

4. While the August 30 decision requires the importing country to issue a compulsory licence *only if there is a patent* on that particular drug in that country, our Ordinance requiring the issue of a compulsory licence by the importing country provides for no exception. As noted in paragraph 7 of my earlier message the "absence of a patent could be for one of many reasons – because no patent was sought in that country, or because the country as an LDC has till 2016 to change its laws to allow product patents for medicines." This specific situation, which is not addressed in our Ordinance, would appear to be at the heart of one of the concerns articulated in the New York Times editorial. To that extent, certainly, our Ordinance exceeds the TRIPS requirements, especially after the Doha clarifications and the August 30, 2003 decision of the General Council. And, to that extent, it would, clearly appear to be a TRIPS plus provision. While paragraphs 3 and 4 of your letter do address the general requirement of compulsory licences for imports, they do not appear to speak to this specific point.

5. The second clarification contained in your telefax that I would like to refer to concerns pre-grant and post-grant opposition to a Patent Application. The baseline naturally remains the patent law prior to the promulgation of the Ordinance, and so we have to assess the impact of only the *changes* here. Before the Ordinance was passed, interested third parties had recourse to 11 grounds for opposing the grant of patents *before their grant,* under sub-section (1) of section 25 of the Patents Act 1970. All but one of these 11 grounds for pre-grant opposition have now been relegated to the post-grant category. Only the earlier 25 (1) (k) remains as a ground for pre-grant opposition, now renumbered as 25(1)(b). To this has been added a new ground, 25(1) (a), on Patentability.

6. If we are to argue the point, as you have, that the avenues for challenging patents have been increased, rather than curtailed, as a result of the amendment we would need to show exactly how, since on the face of it, the evidence seems to point the other way. The opportunity to challenge a patent in a court of law remains largely unchanged by the Ordinance, as do the provisions relating to the Appellate Board, so to make the point we have to look elsewhere. (The establishment of an "Opposition Board" is unlikely to be seen by third parties to a patent as strengthening their hand since it would have the effect of raising the bar, both in terms of costs and the standard of evidence needed to counter a claim).

7. The New York Times believes that "limit(ing) efforts to challenge patents before they take effect" is one of the "two noxious provisions" of the Ordinance. I find this view is shared by some others as well, including sections of the research based Indian pharmaceutical industry. That is not surprising given that pre-grant opposition, which has been largely eliminated by the Ordinance, is a whole different ballgame from post-grant opposition. In the former the patent opponent is on a level playing field; in the latter the advantage drastically shifts to the patentee.

8. The New York Times is, of course, only too familiar with the shenanigans of the US pharma industry. The latter have time and again demonstrated their ability to extract huge

profits from "evergreening" expired patents, even as legal or other challenges work their way slowly through the system. That such patent claims often fail is beside the point. Possession is nine-tenths of the law - and nowhere more so than in the field of patents. Indeed, it is this logic that motivates pharmaceutical patentees to arm themselves with multiple layers of secondary patents, many of which are of questionable merit if not outright bogus. Bristol Myers, for example, had not too long ago, tried to maintain patent exclusivity on an expiring patent by claiming a metabolite - a chemical generated in a patient's body after consuming a drug! The logic is clear: existence of these secondary patents, however dubious, serves to effectively increase the period of exclusivity, since monopoly profits invariably dwarf litigation costs. Consumers are the ones who have to pay the price - in the Prilosec case, every additional day that generic competition was staved of brought Astra Zenca around US$ 25 million! This would explain why the New York Times finds the relegation of pre-grant opposition to the post-grant phase "noxious."

9. I might also point out that the treatment of pre-grant opposition even in respect of the two grounds now allowed in the revised Section 25 is rather cursory compared to the elaborate provisions (in the Act and the Rules) for post-grant opposition. The Ordinance speaks only of a "representation" for pre-grant opposition as opposed to a "notice of opposition" for post-grant challenge. The procedures for the latter are minutely choreographed, including constitution of an Opposition Board, while in the former it is left to the Controller to consider and dispose of the representation in such manner as may be prescribed. There is no provision for a "hearing" in the Ordinance, only in the Rules, where it appears somewhat fleetingly, compared with the elaborate provisions for "hearing" in post-grant opposition. Taken together, these factors have created the impression that for all intents and purposes, opposition proceedings which were earlier essentially pre-grant, have now been pushed back till after the applicant is armed with a patent and firmly entrenched. I might point out that nothing in TRIPS, or our obligation to provide product patents, requires us to eliminate or reduce the grounds for pre-grant opposition.

10. It is self-evident that lax and permissive patentability standards - which the West would like every country to adopt as though it were a *sine qua non* of a modern patent regime - would undermine our national interest. "Evergreening" is a direct consequence of such lax standards. Indeed, now that we have product patents for drugs, vagueness on the question of patentability does not serve our interest - a point implicit in the New York Times editorial. This is the third criticism of the NYT.

11. As we all know, "evergreening" enables pharmaceutical patent holders to extend their patents, "by switching from a capsule to tablet, for example, or finding a new use for the product", as the New York Times puts it. The reason the paper sounds this alarm, I suspect, is because they are uneasy about the amendment involving replacement of the earlier expression "new use" with "mere new use" in section 3(d). The NYT is all too familiar with the practice of "evergreening" by US drug companies. The amendment has evidently fueled fears that we might be laying the groundwork for granting patents for new uses - or even "new methods of use" at

some point in the future. To dispel such fears not only on the part of the New York Times, but more importantly among our own concerned citizens, government might wish to consider incorporating some suitable language which will conclusively foreclose any such possibility.

12. A system that allows Novartis to obtain a patent in India that will guarantee Glivec an exclusive market until almost 30 years after a patent was first filed for the active ingredient in Switzerland, clearly is in need of rectification. If we include clear patentability criteria we should be able to prevent such exploitative use of our laws by the big Western pharmaceutical companies. Member states have complete discretion in defining their own patentability standards in the context of their individual circumstances, taking into account their national interest. I see that the Indian R&D based pharmaceutical industry has been demanding this in the context of our shift to product patents for medicines.

13. Our Patent law itself should be absolutely clear on the standard a patent application must meet for grant of a patent. When the Ordinance comes up before Parliament, it would be a good opportunity for considering this matter. It would, among other things, pre-empt possible adverse developments abroad - for example, in the framework of the SPLT negotiations in WIPO. A clear stipulation prohibiting the patenting of different salts, hydrates, isomers, metabolites, and polymorphs, would prevent our patent system being tied up endlessly by litigation on grounds of patentability. Such litigation would not only be costly for Indian industry and be a drag on its development, the climate of uncertainty that would result would exact a heavy toll. I might mention that providing for pre-grant opposition on the ground of patentability, as has been done in the Ordinance, without clearly spelling out our patentability standard, might be viewed by third parties as a recourse more illusory than real.

14. I agree that a modern patent law is expected to provide a secure and conductive environment to investments, and thereby contribute to faster economic and technological development. However, I don't think anyone would argue that *modern* is equivalent to *making it easier for an applicant to obtain patents* rather than *making sure that only good and deserving patents are granted.* The fact that India has emerged as a leading supplier of quality and cost effective drugs in the world can be traced directly to our stringent - and restrictive - patent laws in the last three decades, not to a permissive patent regime as exists in the United States.

15. We are, indeed, all proud of the rapid stride made by the Indian R&D based pharmaceutical industry. We should not, however, assume that they are already in a position to take on the Western pharmaceutical majors as equals. I think the reality is very different and our industry, impressive as their growth has been in the last 30 years, still needs the full measure of any flexibility available under the international regimes to which India is a party. In particular, they need the flexibility of being able to produce off-patent drugs without having to worry about the proliferation of bogus extensions. By so doing, they hone their skills, which help them to climb the technology ladder, so that in time they can "invent around" the main patent, as more and more of our R&D based drug companies have learnt to do.

16. From there to inventing new, medically useful active ingredients is, however, a big step. Our companies have yet to overcome major technological and resource barriers. Only then should we consider dispensing with the flexibilities that we are fully entitled to under the various international regimes. To that extent, I think the observation in the penultimate paragraph of your letter, where you state "that the Indian industry has also attained global proportions and is adopting research-based development as an integral part of business strategy" could mislead one into believing that our industry can now compete globally on equal terms.

17. I am offering the above views to help the Department of Industrial Policy and Promotion anticipate the likely opposition that the Ordinance could face when it comes up before Parliament. Criticism of the Ordinance by what is unarguably the most influential western newspaper - the New York Times - has to be taken seriously. It would certainly have strengthened the hands of those opposing the Ordinance in India. The Department, in my view, needs urgently to put together additional arguments and a more compelling counter than what is contained in pages 3 and 4 of your letter.

Yours sincerely,

sd/-

(H.S.Puri)

Shri Ashok Jha,
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Department of Industrial Policy and Promotion,
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N.O.O.

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2. Shri S.N. Menon, Secretary, Ministry of Commerce & Industry, New Delhi
3. Shri Shyam Saran, Foreign Secretary, Ministry of External Affairs, New Delhi.

With best wishes,

(H.S. Puri)

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अशोक झा
ASHOK JHA

D.O.No.12/14/2003-PP&C/IPR-III
February 23, 2005

Dear Hardeep,

Please refer to your letter No.Gen/241/4/05 dated 1.2.2005 seeking further clarifications on the provisions of the Patents (Amendment) Ordinance, 2004. As you know the provisions of the Patents (Amendment) Ordinance were drafted after having extensive country-wide and inter-ministerial (Including Ministry of External Affairs) consultations with all relevant stakeholders and interest groups over an extended period of time.

2. Given the fact that there are different and often conflicting interests involved in the several issues covered under the Patents Act we are not surprised that certain sections will oppose certain provisions of the Act. However, all the issues brought out in your letter have been analyzed and discussed in great detail in the past. The proposed amendments are in the overall interest of the country and they embody a fine balance between the interests of the intellectual property creators, holders and consumers. Coming to the issues specifically raised by you, the position is as follows:

Export to Least Developing countries

In fact this provision is wider in the sense that it allows export to any country having insufficient or no manufacturing capacity in the field of pharmaceuticals irrespective of whether that country is a member of WTO. It is not necessary for that country to either have a Patent law or product patent facility for seeking such exports. Moreover, the word 'compulsory licence' appearing in Section 92 (A) can be construed to include an authorization in any form to be granted by that country where there is a public health crisis/requirement for import.

Apart from the provisions under proposed section 92A, section 84 also deals with the issue of export of products. Under section 84 a compulsory licence can be sought on the ground that reasonable requirements of the public with respect to the patented inventions have not been satisfied. The reasonable requirement shall be deemed not to have been satisfied if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, a market for export of the patented article manufactured in India is not being supplied or developed. This addresses the issue of export of products for commercial purposes and/or to countries where either there is no patent law or the relevant product is not covered by the patent.

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Opposition Procedure

In fact the Patents (Amendment) Ordinance, 2004 strengthened the provision relating to opposition as it introduced the concept of hearing at the pre-grant stage.

Regarding the 11 grounds of pre-grant opposition contained in erstwhile section 25(1), I would like to clarify that the grounds of opposition contained in the erstwhile section 25(1) are covered as the grounds such as prior publication, prior claiming, prior public use, non-patentable inventions (Section 3), not an invention and lack of inventive step ([Section 2 (i) (j)] etc. existing before 1.1.2005 would in fact be looked into in any case by the examiner before the patent is granted. Besides, it is obvious that the grounds of novelty, inventive step and industrial application which are in fact the substantial and major grounds for challenging a patent are available. Therefore, these grounds are not diluted but a procedural safeguard has been inbuilt in favour of the third party as well as the patentee to provide a faster decision on a patent application without jeopardizing public interest. In any case an aggrieved person can always make a reference to the Patent Office which the Patent Office is duty-bound to examine as the grounds listed for pre grant opposition are inclusive opposed to the situation prior to the ordinance where the opposition was confined to the grounds listed. Therefore, the opportunity of challenging a patent has not been curtailed.

Evergreening of Patents

The basic criteria of patentability, namely, novelty, inventiveness and industrial application have not been changed. Read with this, the amendment to section 3(d) to include the word 'mere' is not going to result in grant of patent for new uses and thus evergreening is prohibited. The addition of the word 'mere' before 'new use' does not provide any patent for new use of a know substance on the analogy that discovery of a new use of a known process is not patentable under the law although the word 'mere' is already there before these words and provides drafting consistency.

4. I hope this clarifies the issues raised by you based on the New York Times editorial. I would like to mention that these issues are not new having been raised in the past also and we have responded to them adequately.

With kind Regards,

Yours sincerely

(Ashok Jha)

Shri H.S. Puri
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Permanent Mission of India
Geneva