

Point-Counterpoint: Doha Ministerial Meet

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Dr Gopakumar G Nair, Chairman, BDH Industries Ltd, (Letter addressed to the Editor)

The Doha meet of the World Trade Organisation (WTO) is over, so is the euphoria of the Indian pharmaceutical industry. Many clauses agreed upon at the Doha meet have put the Indian pharmaceutical industry in a jinx. Mixed responses have been evoked from industry representatives. The smaller companies are bound to be hit badly while there would be a period of indecisiveness in the case of bigger companies. The only brightening aspect is declaration of certain diseases of national importance.

The granting of compulsory licence to developing countries but mandating setting up of a manufacturing base in the country where the exports are targeted is sure to hit the Indian pharmaceutical companies. The clause granting of compulsory licence does not include a provision of exports for patented drugs. "It is a complete eyewash and there is no gain. Not allowing for direct exports is a major deterrent," said Amar Lulla, joint managing director, Cipla.

He also maintained, pointing out Clause 6 of the "Declaration of TRIPs Agreement and Public Health", that the WTO members with insufficient or no manufacturing facilities could face difficulties in making effective use of compulsory licencing. What makes this clause more stringent is the fact that a company cannot use the manufacturing base in the country for which an export was targeted for exports to other countries.

A government could ask any pharmaceutical company to supply or manufacture a patented drug, if the patentee does not agree to supply at a lower price, under the compulsory licencing clause. In other cases, a pharmaceutical company can apply for a compulsory licence from a patentee and might be granted a licence to develop a patented drug after duly compensating the patentee. B V Raizada, Senior Vice President, Ranbaxy Laboratories, claims that while Indian and other developing countries have asked for freedom to produce and export anywhere in the world the non inclusion of exports has come as a major disappointment.

"It is difficult and sometimes not viable to set up a manufacturing unit in the overseas. A lot of planning goes into it and factors such as demand influence the planning process. A company cannot set up a facility overseas for a single product or more than one product. Further, the clause that the manufacturing unit, if set up, cannot be used for exports to other countries is a harsh one. Such a manufacturing unit is not viable if it cannot be used to export apart from meeting the demand of the said country in which the unit is based," said Lulla.

Supporting Lulla's view, Riazada says that setting up a unit in a country where there is a potential for exports but not so much to warrant establishing a unit is not a viable and practically non-implementable provision. "The demand has to justify setting up of a unit in a country. If the demand which can be sustained by direct exports then there should not

be any need for setting a unit. But the clause ignores this aspect," he added. He claims further that the instruction to the council for TRIPs to find an expeditious solution to the problem of not having manufacturing facilities and access to drugs and report to the General Council before end of 2002 had no stuff as till such a solution is found there would be nothing happening.

The declaration of certain diseases of national importance is claimed as an achievement by Swati Piramal, Director, Nicholas Piramal. She opines that the inclusion of diseases like malaria, tuberculosis, AIDS to name a few as of national importance could force the Indian government to grant compulsory licence to domestic pharmaceutical companies to produce certain patented vaccines. Her contention is however countered by Raizada. He says that while the only gain was the acceptance of public health crisis as national emergency, a clear description of public health crisis has not been maintained. On the other hand, Lulla claims that while there could be a possibility of the Indian government asking a domestic firm to manufacture a patented drug in case of emergency but the same has no value unless it translated into benefit the pharma companies.

(Reported by Santosh Nair, Chennai)

We cant keep crying: Dr G G Nair

The TRIPs Declaration from Doha refers to Public Health. The sub clause (c) on National Emergency is not linked to any other sub clause or the main clause or any other main clause.

In this context I need to draw your attention to all other references to Public Health in the WTO Declarations from Doha. The Concluding Report states - "The declaration on TRIPs and Public Health spells out Minister's recognition of various flexibilities that the agreement gives to governments to deal with health problems". The (Main) Ministerial Declaration says "we recognize that under WTO Rules no country should be prevented from taking measures for the protection of human, animal or plant life or health or of the environment at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on International trade and are otherwise in accordance with the provisions of the WTO Agreements.

Even the decision on "Implementation - related issues and concerns" contains nothing to the contrary on TRIPs (even though there is evidently urgent need for attention on Agreement on Technical Barriers to Trade (TBT), Rules of Origin (RO) and to sub para 1(b) and 1(c) of Article XXIII of GATT (1994).

As far as TRIPs implementation is concerned one thing is very clear in the language of TRIPS "TRIPS Agreement does not and should not prevent members to protect Public Health" (please note it is not referring to public health emergencies whenever it speaks to Public Health).

Further it says "we affirm that the Agreement can be interpreted and implemented in a manner supportive of (India's) WTO members right to protect Public Health and in particular promote access to medicines for all. Most importantly clause (c) is an independent clause. No other clause or sub clause refers to sub clause (c).

We can't keep crying that we didn't get what we asked for or what we should have got. The fear of WTO-DSB is unfounded. We should do what we need to do, including providing compulsory licence for export (considering that Article 33(1)(f) uses "predominantly for domestic consumption" not "exclusively for domestic consumption".

The National emergencies that the clause 5 (c) of TRIPs (Doha) Declaration refers to can be linked by us to the Licence of Right for medicines (Section 86 & 87 of Patent Act, 1970).

All what we need is a positive frame of mind, we will be on track. The dialogue and discussions will go on. We need to look forward with optimism and hope.

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(Letter addressed to the Editor)