

Foreword, March 2008.

Dear Sirs/Friend,

Sub: March 2008 Foreword, www.patentmatics.org

1. In response to the Foreword, February 2008, Prof PV Indiresan wrote thus: “Your piece on the Nano was very touching; the other side of the situation with foreigners gobbling up all our scientific talent is disturbing to the same degree. The GE laboratory on materials in Bangalore is out of this world. There is no Indian laboratory comparable to it. We still do not understand that human capital is more valuable than financial one. I have been director of an up and coming Pharma industry in Hyderabad. The company had an R&D budget of nearly Rs. 100 crores a year. An American one has gobbled one bad investment and the company. A wise government would not have allowed such a take over. There are serious problems but our policy makers are all wool gathering”. More of the TRIPS related issues, later in the Foreword.

2. The Indo US (123) Nuclear Agreement is truly being pushed to proceed in the “right” direction with the US, so much interested in India’s Energy Security, cajoling GOI to shed its diffidence and to go for it firmer, faster and in true cooperative spirits! To summarize the very recent incidents,

(a) Feb. 20: three influential US Senators - Joseph Biden, John Kerry and Chuck Hagel - after a meet in g with Prime Minister Manmohan Singh said the negotiations with IAEA and NSG should conclude by May fail in g which New Delhi will not get a "similar" deal when next government is formed in Washington. The lawmakers told S in gh that if the deal, which faces stiff opposition from his government's Left allies, is not taken up the US Congress by June and the process completed during the tenure of President George W Bush, any new US administration will "renegotiate" the agreement.

Senator Joseph Biden, chairman of the Senate Foreign Affairs Committee, warned the Indians that a civil nuclear agreement had to come before the Senate for approval no later than July. "Time is of the essence," Biden said. If we don't have the deal back with us clearly prior to the month of July, it will be very difficult to ratify," Biden said. He also said it was "highly unlikely" the next president would be able to authorize the same deal, if it did not reach Congress in time. "It will be renegotiated," he said. **"It is critical, if India want that deal, they move on relatively soon, with in a matter of weeks," he said.**

(b) 26 February: In response to Biden’s warn in g, the White House said Tuesday there was a "bit more time" in the US political calendar before President George W. Bush leaves office.

© 27 February: US Defense Secretary Robert Gates warned Wednesday that **"the clock is ticking"** on a US-Indian civilian nuclear accord. "The clock is tick in g in terms of how much time is available to get all the different aspects of an agreement implemented," Gates told reporters in New Delhi . He said the deal "serves the best interests of both countries".

(d) 29 February 2008: Burns asked the Indian government to take a “courageous” decision on the civilian nuclear deal consider in g the “short timel in es.” “If you back up from there, that means that **the IAEA agreement must be made with in a week or two,** and it means the NSG would have to begin acting in the month of March. So there are very short timelines here, and I’m afraid it’s time for the government to decide,” he said. Mr. Burns said, **“If India is to be given this great victory, there has to be a courageous decision made by the government to move forward. We hope that decision will be positive.”**

(d) March 1: Strobe Talbott was reported as having said that if the Clinton administration, which was deal in g with the Vajpayee government, would have been prepared to offer only “half” of what the Bush administration had offered the Manmohan Singh government, “the Indian side [the Vajpayee government] would have gone for it.” "The Clinton administration negotiated with the BJP-led government on the nuclear issue and that know in g what the goals of my Indian interlocutors at work at that time and see in g how those goals compare with the current Indian government has gotten out of President Bush by way of the civil nuclear deal, I can't understand how is that the BJP could oppose the deal as it obviously does," he told *Walk the Talk* programme on NDTV. "I think half of what the Clinton administration has been prepared to offer the BJP-led government that we were deal in g with, the deal that President Bush was will in g to make with Manmohan Singh and company, the Indian side then would have gone for it," said Talbott, known in India for the two-year marathon talks with the then External Affairs Minister Jaswant Singh.

(e) March: Richard Boucher, US assistant secretary of state for South and Central Asian affairs, arrives for a two-day trip to discuss the deal.

These developments are in addition to a recent clarification on the subject by none other than Added to all the above was a recent statement of Condoleezza Rice herself. According to a PTI report dated Feb 14 from Washington, the Bush administration has said an agreement between India and the U.S. will support the Nuclear Suppliers Group, which will allow New Delhi to engage in nuclear trade, only if it is “consistent” with the Hyde Act. “We will support nothing with India in the NSG that is in contradiction to the Hyde Act. It will have to be completely consistent with the obligations of the Hyde Act,” Secretary of State Condoleezza Rice told the House Foreign Affairs Panel. Ms. Rice said if the Bush administration did not adhere to the Hyde Act — which, according to opposition parties in India, takes away the country’s nuclear sovereignty — U.S. lawmakers will eventually refuse to pass the India-U.S. civilian nuclear deal if and when it comes up in the Congress. “We’ll have to be consistent with the Hyde Act or I don’t believe we can count on the Congress to make the next step,” Ms. Rice said in response to a query from the Chairman of the panel, Howard Berman.

Amazingly enough, Mr Talbott was not asked about the well known “ Clinton’s Four Point NPT Bench Marks” described in his now well-known “Engaging India” on the subject and his unequivocal statement therein how the then government headed by BJP had rejected them for the former’s own reason! For strategic analysts like Raj Mohan, “That the BJP’s opposition to the nuclear deal is bereft of all principle is no secret,... the CPM’s very definition of national interest has always been out of sync with that of the national mainstream”. *In other words, it is championed that only the policy of the “minority” UPA is in line with national interests, all others constituting a sizeable majority in parliament are against national interests. The latest policy statement of the Foreign Minister in Lok Sabha that GOI does not recognize Hyde Act does not mean ipso facto anything more than what he had all through been repeating ad nauseam, since the 123 Agreement itself is subject to the respective national laws; and if GOI does not go by Hyde Act of US, the 123 Agreement is itself null and void unless US amends its Hyde Act. Truly tough days for our hapless nation.* Fortunately enough, opposition for the Agreement is not restricted to the non-UPA political leadership alone. Thus (a) “It was a mistake for India to have parked the nuclear agreement in an Indo-U.S strategic relationship. But continued exclusion from international civil nuclear

commerce will deprive India of a voice in managing emerging nuclear problems” wrote Dr MR Srinivasan, former Chairman/AEC in a recent article in The Hindu. (b) Atomic Energy Commission chief Anil Kakodkar is quoted recently as saying (quoted from Live Mint), “If we are following a standard template, then it’s one story, that much easier. (But since this is the first time) it takes time,” India and IAEA have held four rounds of talks since November, but failed to firm up the agreement, which is a crucial step for implementation of the Indo-US nuclear deal. The two sides have differences on issues such as allowing India to create strategic reserve for the lifetime of its civilian nuclear plants and corrective measures in the event of stoppage of fuel supplies because of any reason. Besides these conditions, India has been insisting on IAEA’s acknowledgement of its strategic programme by accepting the Separation Plan finalized with the US. The last round of talks was held in the third week of January. The two sides were to meet again in the middle of this month, but no dates have yet been fixed. Asked if the time was running out for the Indo-US nuclear deal, Kakodkar said: “The point is we have to get this done as early as possible, but it has to be correctly done and it has to meet all the requirements and so it’s a long technical process. There are several steps. We have to go through step-by-step.” “There are complex issues. You have to deal with them one-by-one. It will take time. But it’s moving forward. We hope to do it as soon as possible,” Kakodkar said.

Asked about the “implications” for the US and India if the deal does not go through, Kakodkar said: “We should continue our efforts. I will keep working for it. We should keep making our honest efforts.”

If even an NPT country such as China had taken years to sort out her issues with the US, is it right for the UPA government to push AEC through the deal in such hurry? *Obviously, it will not work that way, as long as parliamentary democracy is alive in India! And this thrust for nuclear power when, according to reports, power generation targets may fall victim to delays in government clearances. India has a power generation capacity of 140,000MW and plans to add 78,577MW by 2012; of this, only 7,263MW has been commissioned. Delays in timely forest and environmental clearances for 30 thermal power projects may make it difficult for India to meet its already ambitious power generation targets.*

3. Since the GOI amended the 1970 Patents Act to make it TRIPS compliant, ignoring the views of many that “patents are granted to encourage inventions and to secure that inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practical without undue delay and that they are NOT granted merely to enable patentees to enjoy a monopoly for the importation of the patented article”, new and serious issues have started coming up in the field of drugs. For the first time since the said amendment, reports Live Mint,

local drug makers are exploring the possibility of using a controversial provision of the Trade Related Intellectual Property Rights (TRIPS) agreement of the World Trade Organization (WTO) that allows member countries to permit firms to make cheaper versions of such drugs.

Known as [compulsory licensing](#), this provision can be invoked by a country if a drug maker is willing to make and supply copies of patented drugs in a medical emergency or to export to least developed countries, which are yet to be covered by the TRIPS regime. Setting off what could become a trend, Hyderabad-based cancer specialty company Natco Pharma Ltd has requested the government to grant it a compulsory license for two high-cost drugs: Sutent, a renal cancer drug of Pfizer Inc., and Swiss drug maker F Hoffmann-La Roche Ltd’s lung cancer medication, Tarceva. Both drugs are currently protected under global patents. “We have applied for granting compulsory license for Erlotinib, the generic version of Tarceva, and Sunitinib (Sutent) to the government,” Natco’s chief operating officer Rajeev Nannapaneni said. Cipla Ltd, one of the country’s top three drug makers, has similar plans. The target of

compulsory license requests are largely new cancer drugs already launched by multinational firms under patent protection. Often, these drugs are priced at the same level across the world. Tarceva, for instance, costs about Rs1.5 lakh for a month's treatment. Another cancer drug, Glivec, marketed by Novartis AG, is priced at Rs1.2 lakh for a five-week treatment cycle. Pfizer's Sutent, currently awaiting a patent grant in India, too, is likely to be priced on a par with the international price of \$4,000 for a six-week treatment cycle. "The improved operating environment (IP and regulatory) in India has enabled Pfizer to rapidly bring Sutent to patients in India... Recognizing that affordability of cancer treatment can be a challenge, Pfizer has also developed a Sutent Patient Assistance Programme (SPAP)..." a Pfizer spokesperson said. India has one of the widest compulsory licensing provisions in the world. **The country's patent law provides for compulsory licenses to be issued if the drug in question is not available in adequate quantities locally and also when the government feels the drug is not reasonably priced.** It is in this context that Cipla is fighting a case in the Delhi high court to justify its plan to launch a low-cost version of Tarceva in the local market. Cipla says it wants to sell the drug at Rs1, 600 a tablet, one-third of its market cost. Natco wants to price it at about Rs1, 000. "Access to these medicines is a serious issue in a country like India if these are granted monopoly rights without merits. When generic companies can produce these drugs at one-third or one-fourth of the price, it should be encouraged," said Cipla chairman Yusuf K. Hamied. In April, Union health minister Anbumani Ramadoss had asked Novartis to withdraw a patent litigation it is engaged in India over Gli-vec and warned that the country should not be forced to "issue a compulsory license" even though it had never issued one. Novartis has not withdrawn its case and Ramadoss has not taken any action yet.

Patent experts say there are several clauses in Indian patents law that local drug makers can use to push for compulsory licenses. Patent holders, for instance, are not allowed to claim their product prices are high because they do not have manufacturing facilities in the country. In such a scenario, the government can permit a local drug firm to make and sell the patented product at lower prices. **Most of the patented drugs of multinational drug firms are imported today.**

Next, said Shamnad Basheer, an associate at the Oxford Centre of Intellectual Property Studies, patent rules allow multinational pharmaceutical firms, when granted a patent, a lead time of three years to bring the prices of their drugs to a level that does not inhibit patient access to the drug. After three years, if the government is convinced that the use of the drug is limited because it is not affordably priced, it can issue a compulsory license to a drug maker that promises to bring prices down. "As of today, this can certainly kick in for a number of pharmaceutical process patents that were granted more than three years back," Basheer said. There is a third provision in the Indian Patents Act to enable a compulsory license: if a globally patented drug was being manufactured in India prior to 2005 by a local drug maker, it, too, can be allowed a licence. Patents on drug products were allowed in India since January 2005, before which only processes to make drugs could be patented. "India has some outstanding generic companies that can exploit compulsory licensing provisions. In countries like Nepal or Bhutan with no adequate manufacturing capacity, such compulsory licensing provisions may be of no use..." said Gopakumar Nair, chief executive of Gopakumar Nair Associates, a Mumbai intellectual property advisory firm. According to the Doha Declaration of the WTO, compulsory licenses to export to least developed nations have been made TRIPS-compatible. The rules mandate that the importing country must notify the WTO's council for TRIPS of the name and expected quantity of the product, verify that it has insufficient or no manufacturing capacity for the product, and confirm that it has granted or intends to grant a compulsory license. Still, in all these instances, it is the WTO member-country's responsibility to ensure and prove that its intent on compulsory licensing is in public interest. "In fact, it is widely thought that owing to the various preconditions, it is onerous to apply for and operate such a license," said Basheer. **Late in 2006,**

Thailand issued a compulsory license for Merck and Co.'s HIV/AIDS drug Efavirenz in a bid to cut growing health care costs. The Thai government then argued that products imported from India cost half that of Stocrin, Merck's branded treatment.

This development is in addition to those like the anti cancer drug Glivec of Novartis on which fortunately the Chennai HC gave a historic judgment rejecting the claims of Novartis. There is obviously a very urgent need to produce large number of IPR experts both within the judiciary and outside in our country within a reasonable time frame, failing which the nation will suffer irreversible loss of lives due to inadequate availability of drugs at affordable costs. Amazingly enough, even the Budget Speech of the FM is indifferent on steps to promote drug R&D in the country as well!

The situation is not much different in new seeds for agriculture as well. According to a BL article by a well known expert in the field K P Prabhakaran Nair "India has been unable to bring out a desi Bt cotton while a particular MNC had a "very rich harvest" of profits through the "Bollgard" cotton in 2003. This did not happen in China, where cotton scientists affiliated to the Chinese Academy of Agricultural Sciences worked hard for almost a decade. They brought out a Chinese variety of Bt cotton and the MNC had no other option but to sell a 450-gm seed packet for just under \$2, while the Indian farmer had to cough up close to \$50 at the time Bollgard was released in India for commercial cultivation, until politicians and the farmers lobby started to cry hoarse to bring the price down to under \$20". And this situation continues even when, according to BL itself, . According to Rajesh Kochar, the well known science policy expert and former Director of NISTADS of CSIR, "It is an extraordinary situation that the most momentous scientific development in the history of humankind, concerning the vital commodity of food, is not driven by curiosity but commerce. Nobody views GM technology as the fruit of collective human effort. Rather it is seen as a handiwork of localized commercial interests. It has been noted "many of the arguments that are used against GM crops are really arguments against the misuse of power by large multinational companies." GM crops have become a symbol of broad opposition to globalization and American domination". Again, BL reports," Between 2002-03 and 2007-08, the country's cotton production has shot up from 136 lakh bales (of 170 kgs each) to an estimated 310 lakh bales. While some of this may be due to a near-quarter jump in area sown (from 76.67 lakh hectares to 95.3 lakh hectares), more significant though is the contribution of yields, which have gone up from 302 kg to 553 kg (lint) per hectare.

But how much of the higher yields have been a result of Bt cotton, which coincidentally was introduced in 2002 and covered 62 lakh hectares or almost two-thirds of the total cotton area in 2007? According to Dr C.D. Mayee, Chairman of the Agricultural Scientists Recruitment Board (ASRB), "There is no doubt that at least 50 per cent of the yield increase is attributable to Bt technology..... In both India as well as China, the entire GM area is under a single crop – cotton. In fact, the 6.2 mh under GM cotton in India represents two-thirds of the total 9.4 mh under the crop, "a remarkable achievement in a period of just six years". In essence, if the BT gene also is subjected to Compulsory Licensing and made available to Indian entrepreneurs for producing their generic versions, the Rs 60,000 waiver by the Finance Minister would have concurrently also added truly perennial support as well. So also implementation of the now well discussed Minimum Remunerative Prices concept for them. **The Bt Case is another TRIPS dictated curse for the nation!**

Looking forward to your views and suggestions,

Yours sincerely,

A D Damodaran