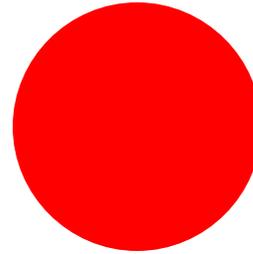


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Mashelkar's Folly: A Critique of the Technical Expert Group Report on Patent Law Issues

- Gopa Kumar¹

(Mashelkar has resigned as we go to press. But there is still a real danger of his recommendations being recycled by a new committee. Even as Novartis and others use the recommendations to their advantage in the Gleevec/Glivec case in Chennai High Court. We therefore carry this and related articles in this issue as the fight is still on. – Editor, mfc bulletin)

The report of the Technical Expert Group on Patent Law Issues (Mashelkar Committee) has submitted its Report to the Ministry of Commerce and Industry, Government of India on 29th December 2006. The Report was made available to the public on 12th January 2007. This Committee was established with the following terms of reference:

- a) whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps; and
- b) whether it would be TRIPS compatible to exclude micro-organisms from patenting

The Committee has made the following recommendation to the government with regard to the scope of patent protection to new chemical entities.

“In the light of the above discussion, it would not be TRIPS compliant to limit granting of patents for pharmaceutical substance to New Chemical Entities only. However, every effort must be made to provide drugs at affordable prices to the people of India. Further, every effort should be made to prevent the grant of frivolous patents and ‘ever-greening’. Detailed

Guidelines should be formulated and rigorously used by the Indian Patent Office for examining the patent applications in the pharmaceutical sector so that the remotest possibility of granting frivolous patents is eliminated.”

The following paragraphs offer a critique on the major findings of the Committee with regard to the above recommendation and major findings of the Committee, which lead to the above recommendation.

1. The terms of reference clearly mentions that task was to find *whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps*. However, the Committee does not answer this question and also cites the so-called national interest to make its recommendation. The reasons cited in the Report for making the national interest argument are based on certain assumptions which are either irrational or highly contested ones. According to the Committee “*Granting patents only to NCEs or NMEs and thereby excluding other categories of pharmaceutical inventions is likely to contravene the mandate under Article 27 to grant patents to all ‘inventions’. Neither Articles 7 and 8 of the TRIPS Agreement nor the Doha Declaration on TRIPS Agreement and Public Health can be used to derogate from this specific mandate under Article 27*”.

With these two lines the Committee concludes that limiting the scope of patentability to new chemical entities would violate the TRIPS obligation under Article 27. In other words the Committee brushes aside their mandate, i.e., to examine the above legal question and indulges in rhetoric. The Committee is expected to

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give its reasons whatsoever they may be in making the above assertions. A quick analysis is attempted in the following paragraphs to show the merits of the Committee's view, i.e., *it would not be TRIPS compliant to limit granting of patents for pharmaceutical substance to New Chemical Entities only.*

2. Firstly, the Committee fears that limiting the scope of patentability to NME /NCE is likely to contravene the mandate of TRIPS. Further the Committee states that Articles 7 and 8 as well as Doha Declaration on TRIPS Agreement and public health cannot be used to derogate the mandate under Article 27. This conclusion of the Committee is based on superficial analyses (the Committee does not give any reason for even this conclusion). Article 27 creates two obligations which are relevant our discussion. Firstly, both products and process patents should be available to inventions in all fields of technology provided they are new, involve inventive step and capable of industrial application. Secondly, availability and enjoyment of rights should not be discriminated on the basis of place of invention, field of technology or place of manufacture.

The first obligation is that product and process patents should be made available to inventions. However, availability does not mean grant of patents to all patent applications. Grant of patent is based on applicant's ability to satisfy patentability criteria and any other relevant requirements. According to Article 27, patents are granted to an invention. Significantly TRIPS does not offer any definition for invention and only mentions the basic requirements of an invention to become eligible for patent protection. This gives a lot of freedom to member states to determine the meaning of invention as well as to exclude applications for secondary patents from patent protection. Patents for new drug use or a new combination of drugs can be excluded from patent protection by defining invention in that manner. Further all inventions become eligible for patents only when they satisfy all the three criteria, viz., novelty, inventive step and industrial application. Since TRIPS leaves it to member countries to define these three criteria, this gives an opportunity to the implementing country to determine the scope of patentability, i.e., will it be limited to new chemical entities or will it also include incremental innovations (not inventions). Since most of the incremental modifications/innovations fails to satisfy the high threshold level of patentable criteria, they would not be eligible for patent protection.

3. According to the second obligation under Article 27 what is prohibited is the discrimination of availability and enjoyment of patent rights on the ground of place of invention, field of technology, place of manufacture. This means that discrimination on other grounds is permitted. Further, the prohibition is only against

discrimination and not on the differentiation. In other words differentiation is still permissible. The WTO Disputes Panel also recognized this reasoning in the EC - Canada Case (*WT/DS 114*). Therefore limiting the scope of patentability to new chemical entities does not violate the obligation of non-discrimination as to the field of technology under Article 27(1). Thus it cannot be argued that limiting patentability to new chemical entities would be discriminatory as the limitation would only be with respect to the pharmaceutical sector.

While upholding the Bolar provision the Panel held that: "*Article 27 prohibits only discrimination as to the place of invention, the field of technology and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.*"

4. Again as stated earlier, the word *availability* does not mean the grant of patent in all circumstances. The non-discriminatory provision does not prevent member countries to fix the threshold of patentability criteria. The patentable criteria are applicable to all fields of technology and do not discriminate against any technology. Therefore every country has a freedom to fix a high level of threshold for patentable criteria and the exclusion of discoveries from patentability would not be incompatible with TRIPS obligation. Therefore TRIPS leaves it to member countries of the WTO to define certain key provisions that determine the scope of patentability.

The Agreement permits States to "*determine the appropriate method*" to implement the provisions of the TRIPS Agreement within their legal system. There is a legislative flexibility within the TRIPS framework to determine the scope of patentability by providing suitable definitions to the three basic criteria of novelty, inventive step and industrial application. The Committee has not either examined or stated reasons in its report on these methods of restricting the scope of patent protection.

5. The objective of TRIPS is mentioned in Article 7 which states "*the protection and enforcement of intellectual property rights should contribute... to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare....*" On the objectives of TRIPS, India's submission states: "*...patent rights should be exercised coherently with the objectives of mutual advantage of patent holders and the users of patented medicines, in a manner conducive to social and economic welfare and to balance of rights and obligations. Where confronted with specific situations*

where the patent rights over medicines are not exercised in a way that meets the objectives of Article 7, Members may take measures to ensure that they will be achieved....”

India’s socio-economic context, where millions are unable to access the public healthcare system requires that it balance the right of access to affordable medicines with patent rights. While the introduction of product patents is of great advantage to pharmaceutical companies who hold patents, restricting patent protection to new chemical entities will provide relief to Indian patients who will be able to access affordable pre-1995 drugs produced generically.

6. Further, principles of implementation under Article 8 states “*members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio economic and technological development....”*

According to India’s submission, “*any interpretation of the provisions of the Agreement should take into account the principles set forth in Article 8. The reading of such provision should confirm that nothing in the TRIPS Agreements will prevent Members from adopting measures to protect public health, as well as from pursuing the overarching policies defined in Article 8.*” Hence, India is free to limit the scope of patentability to new chemical entities in its Patents Act to protect public health.

7. It is a well known rule that any treaty obligation should be interpreted in the light of its objectives and principles. This was further stated in the Doha Declaration on the TRIPS Agreement and Public Health which states that “each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.” Hence, every member country has the freedom to limit the scope of patentability.

8. On the question of whether Doha Declaration on the TRIPS Agreement and Public Health supports the limitation on scope of patentability the answer is a big “Yes”. According to the Doha Declaration, “*We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.*” (Para 4)

There is no doubt that measures like limiting the scope of patentability to new chemical entities is to protect public health by reducing the number of monopolies in the pharmaceutical markets. A lesser number of patents would provide space for generic companies and promotes access to medicines. Thus any measures on restriction of scope of patentability should be interpreted in the light of Para 4 of the Declaration and the WTO Dispute Body is to give due consideration to such measures if it is for protecting public health. The Committee totally ignores these facts while making its assertion that “*Neither Articles 7 and 8 of the TRIPS Agreement nor the Doha Declaration on TRIPS Agreement and Public Health can be used to derogate from this specific mandate under Article 27.*”

9. The demand for restriction of scope of patentability for the pharmaceutical inventions came up in India for two reasons: Firstly, on public health grounds and secondly on adverse effects of misuse of patents on the generic industry. Unfortunately, the Committee has not addressed the implications of extending patent protection to evergreening and incremental modifications of a known chemical substance on access to medicines and public health. The Committee sets three arguments under the heading “National Interest Perspective” to support its view on patent protection for incremental modifications/innovations. The so-called national interest perspective considers only the interests of a few big Indian pharmaceutical companies (the merits of the argument are discussed in subsequent paragraphs). There is no reference to public health concerns in the report. This forces one to wonder that whether public health is not a factor while considering national interest.

10. However, the Committee is of the opinion that, “*It is important to distinguish ‘ever-greening’ from what is commonly referred to as ‘incremental innovation’.* While ‘ever-greening’ refers to an extension of a patent monopoly, achieved by executing trivial and insignificant changes to an already existing patented product, ‘incremental innovations’ are sequential developments that build on the original patented product and may be of tremendous value in a country like India. Therefore, such incremental developments ought to be encouraged by the Indian patent regime.”

Hence the Committee attempts to make a distinction between evergreening and incremental innovation. However, the Committee ignores the fact that both have the same effect in practice especially considering their implications for access to medicines. It is also to be noted that according to Indian Patents Act a patent is granted for inventions and innovations. The same view is reflected in its recommendation. It is a well known fact that detailed guidelines alone are of little help in

preventing evergreening and frivolous patents without statutory support. Further, the present infrastructure of the Indian patent office does not support this view.

11. According to the Committee, *“Restricting patentability just to NCEs or NMEs could have both legal and scientific ramifications. There is a perception that even the current provisions in the Patents Act could be held to be TRIPS non-compliant. Drug discovery research is still finding its feet in India. Though many companies are investing, it will at least be a decade before a critical mass is in place and results start accruing. Thus, restricting patentability to just NCEs would mean that most of the pharmaceutical product patents would be owned by MNCs.”*

Thus the Committee states that Indian industry should be allowed to patent incremental modifications/innovations in order to help them to graduate to patent NCE. This is a baseless argument. Patenting and product development are different. There is ample evidence suggesting that Indian companies have patented many new molecules in India and abroad. However, what they are lacking are the resources for developing it as product. Hence, this view of the Committee is contrary to reality. Further, there is no basis in the view that only through patenting of incremental modification will one be capable to patent NCEs. Furthermore, the Committee totally ignores the fact that limitation on patenting would help the generic manufacturers to use the NCEs more quickly and benefit the Indian industry. Here the Committee went out of its way to make a suggestion that Government should promote patenting of incremental modifications/innovations. Lastly, the biggest beneficiaries of patenting of incremental modification are multi national pharmaceuticals. There is ample evidence to show the patent rights manipulation of MNCs. The Committee recommendations are totally in line with the MNC argument that patenting of incremental modifications helps the Indian companies and not the MNCs.

12. According to the Committee: *“In case of patenting of drugs, the protection to various forms of same substance (salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixture, etc.) is often seen as ‘ever-greening’ (extending incremental protection to a subsisting patent) and hence such protection is objected to. In most countries, patenting of an invention for different forms of the same substance is subjected to the test of novelty, non-obviousness (unexpected effect) and utility before it is granted patent protection. Such a protection in the form of incremental inventions in respect of known and new molecules or a process potentially provides*

an added advantage to an inventor or a firm to retain its market share or capture a space in the established market. However, patenting an invention does not imply that a person can practice the invention; he would have to exercise due diligence and ensure that the rights of others are not infringed.”

Here it is very clear that the Committee does not consider the public health implications of extending patent protection to incremental modifications. It may give an advantage to a firm for capturing market or to retain a market share but there is also a fact that such attempts would act as barrier to access to medicines. Further, too many patents on a single substance in practice kills the theoretical rhetoric of the Committee that patenting an invention does not imply that a person can practice the invention. Too many patents on the same substance would lead to a patent thicket and makes the due diligence practically impossible.

13. According to the Committee, *“Many drug industry stakeholders feel that the use of the expression ‘new chemical entity’ under the Patents Act would lead to many interpretations. While some Indian drug industry representatives feel that limiting grant of patents to new chemical entities will not be conducive to competitive growth, some others feel that patent protection should only be given based on the strict compliance of the patentability criteria. Many Indian industry representatives are not in favour of widening the scope of patentability. The group examined the current level and type of R&D innovations that the Indian drugs and Pharma industry was undertaking. Annexure IV and V provide some representative samples of international patents filed by the Indian industry. It is clearly seen that most of them are based on incremental inventions.”*

Here the Committee tries to argue that since Indian companies are patenting incremental modifications abroad India should reciprocate. However, we believe that patent policies are determined on the basis of developmental concerns including public health concerns. Hence, patenting of incremental modifications elsewhere should not be a ground for us to do the same in India. Lastly, such patenting is also used by some companies as a defensive mechanism to prevent others from obtaining monopoly rights in such markets.

(Paragraphs 3, 4, 5, 6 & 7 are from our submission to the Committee on behalf of Affordable Medicines and Treatment Campaign (AMTC). Along with the author, Anand Grover and Leena Menghaney drafted the submission.)

*Report of Technical Expert Group on Patent Law Issues***Statement by Scientific and Public Interest Groups**

1. During debate in Parliament in April, 2005 on Patents (Amendment) Bill 2005 senior Members of Parliament pressed for amendments to sub-section (ta) of Section (2) and sub-section (j) of Section 3 of the Patents Act 1970. The Members urged that the definition of 'pharmaceutical substance' should be changed to limit the grant of patent for "pharmaceutical substances to include only chemical entity or medical entity involving one or more inventive steps." The other issue pressed by the Members was about "excluding of micro-organisms from patentability."

2. The Minister for Commerce and Industry gave an assurance on the floor of the House of Parliament that both the issues would be referred to a Technical Expert Group to examine the compatibility of the Members' demand with the provisions of the TRIPS Agreement. Accordingly, the Government set up the Technical Expert Group with Dr. R.A. Mashelkar, the then Secretary, Department of Scientific and Industrial Research and Director General, CSIR as its Chairman with four other members on April 5, 2005. The Technical Expert Group has since submitted its Report to the Government on December 29, 2006. The Report is also available to the public.

3. The Technical Expert Group has concluded that "it would not be TRIPS compliant to limit granting of patents for pharmaceutical substance to new chemical entities." Similarly, in regard to the patenting of micro-organisms, the Group has concluded that "excluding micro-organisms *per se* from patent protection would be violative of the TRIPS Agreement." The conclusions reached by the Technical Expert Group are totally biased and without cogent arguments and are not based on the clarifications provided in the Doha Declaration on TRIPS Agreement and Public Health which "affirms that the Agreement (TRIPS) can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." This clarification is significant enough for exercising our right to determine the scope of patentability for pharmaceutical substances and micro-organisms which are crucial to promote access to medicines for all.

4. The Technical Expert Group has also very conveniently ignored the recommendations of the high level authoritative international studies, such as, the Report of 2002 on 'Integrating Intellectual Property Rights and Development Policy' undertaken by the Commission on Intellectual Property Rights set up by

the British Government and another Report of 2006 on 'Public Health, Innovation and Intellectual Property Rights' Report of 2006 by the WHO Commission on IPRs, Innovation and Public Health. Both these international bodies have unambiguously clarified that "since there is no definition of invention in the TRIPS Agreement, developing countries may determine in their own ways, the definition of an invention, the criteria for judging patentability, the right conferred on patent owners and what exceptions to patentability are permitted." What is more, the UK IPR Commission has specifically recommended that developing countries should aim at "limiting the scope of subject matter that can be patented." The Chairman of the Technical Expert Group, Dr. Mashelkar, was an important member on both these Commissions. Furthermore, Mashelkar Committee on R&D set up by the Government of India, in their Report of 2001 also recommended that "pharmaceutical patents should be granted only for medical entity/chemical entity."

5. In addition to the Reports of the two eminent Commissions and the Committee mentioned above, a joint study conducted by experts of the South Centre, Geneva and WHO, viz., Sisule F. Musungu and Cecilia Oh, and another comprehensive study by an eminent patent expert Professor Carlos M. Correa, who was also member of the two Commissions mentioned above have confirmed the unfettered right of developing countries to define the scope of patentable subject matter for implementation of the TRIPS Agreement.

6. Based on the stipulations of the Doha Declaration, the conclusions of the eminent Commissions stated above and other important studies, the brain-storming meeting came to the unanimous conclusion that the views expressed by the Members of Parliament for limiting the scope of patentability of pharmaceutical substances and that of micro-organisms were entirely in line with the sovereign rights of our country to implement the TRIPS Agreement in a manner meeting our national and public interest. To further substantiate our sovereign rights we have provided in our Patents Act in Section 4 to exclude patenting of all inventions relating to atomic energy and that in Section 39 in the area of national security broadly if the invention is relevant for defence purposes, the prior consent of the Central Government would be needed for grant of patent. Thus, unfettered freedom under the TRIPS Agreement has already been exercised by our country and in the same way, right should also be applied to determine the scope of patentability for pharmaceutical

substances and micro-organisms.

7. As regards, the patentability of micro-organisms, those that occur in nature, such organisms can be categorized only as discoveries and not inventions. Discoveries as such are not patentable. However, in the case of micro-organisms created as a result of human intervention whether by using techniques of genetic engineering or any other technique or otherwise, the activity performed by such micro-organisms would be eligible for process patent only. Keeping this in view, patentable micro-organisms should be defined clearly in our amended Patents Act. Similarly, the stipulation relating to patenting of micro-organism in Section 3(j) in the amended Patents Act should be amended and applied only after the conclusions of the mandated review of the subject of patentability by WTO provided in the TRIPS Agreement in Article 27.3(b) have been completed and are known.

8. The Technical Expert Group have stated that some Indian drug industry representatives feel “that limiting grant of patents to new chemical entities will not be conducive to competitive growth.” The Technical Expert Group also felt that “incremental innovations are sequential developments that build on the original patented product and may be of tremendous value in a country like India and, therefore, such incremental developments ought to be encouraged by the Indian patent regime.” There is, however, no basis or reasons provided to support these contentions. In fact, it should be fully understood that any loose scope of patentability would be exploited more by the multinational corporations (MNCs) rather than by the domestic enterprises. The national interest lies in strengthening of the domestic industry as a whole. The interest of a few large domestic enterprises cannot be construed as the national interest.

9. We may like to emphasize that certain technological innovations to pharmaceutical patented products may qualify for patentability criteria for protection under the patent system. However, such technological innovations can and should be protected only through process patent. The other possibility is that if there is significant technical advance over the invention claimed in the first patent, it is possible to grant dependent patent. Our Patents Act 1970 in Section 91 provides for licensing of related patents based on conditions stated therein. These available possibilities could be suitably availed by the industry. In so far as evergreening of patent issue is concerned, the same can be taken care of only through legal provisions in the Patents Act itself and not through Patent Rules or Guidelines.

10. Limiting of patentability of patented subject matter

is extremely important for our country to avoid chaos and high cost of health care through monopolization of products. The loose definition of patentable subject matter in US Patents Act has resulted in over 17 lakhs live patents, “a wide range of such patents are ‘questionable’ as they are based upon incremental modifications of their products, including minor features, such as, inert ingredients and the form, color and securing of tablets.” These are the findings of high level studies in USA. Our country cannot afford to have a similar unmanageable scenario and hence limiting of patentable subject matter as recommended by UK IPR Commission is important and applied in our Patents Act. If the recommendations of the Technical Expert Group are not rejected, the issue of affordability and accessibility of medicines to our people would steeply worsen, particularly in view of the rapid increasing disease burden in our country. The overall role of domestic enterprises would also be seriously affected not only for meeting domestic needs but also in contributing to meeting such demands throughout the developing world.

11. For all the above reasons, the brainstorming meeting of the experts of the scientific and public interest organizations unanimously rejects the Report of the Technical Expert Group and strongly urge the Government of India that the desire of the Members of Parliament expressed on the floor of the House of Parliament during debate in April 2005 should be respected and necessary amendments carried out to the amended Patents Act, 1970 to avoid policy related and management chaos in the administration of provisions relating to scope of patentability and treatment of micro-organisms as also creation of a high cost health care economy flowing from excessive patent protection. This approach will also ensure an effective role of the domestic enterprises to promote access to medicine for all as recommended in the Doha Declaration on TRIPS Agreement and Public Health.

12. In the national interest this Statement is submitted to the Government of India and State Governments, circulated to representatives of people in Parliament, the national press and eminent citizens of our country.

(S.P. Shukla), (Prof. Ashok Parthasarathi), (B.K. Keayla), National Working on Patent Laws; (Dr. Vandana Shiva) Navdanya; (Dr. Devinder Sharma) Forum of Biotechnology and Food Security; (K.M. Gopakumar) Centre for Trade & Development; (Dinesh Abrol) CSIR Scientific Workers' Assn; (Dr. Amit Sen Gupta) Delhi Science Forum; (Dr. Mira Shiva) All India Drug Action Network

New Delhi, February 16, 2007

The Glivec Story: Some Key Dates ¹

- 1994/1995 - Creation of the World Trade Organization & starting date of the TRIPS Agreement in force, which obliges developing countries to grant patents on medicines no later than 2005.
- India has around 30,000 cases of Chronic Myeloid Leukemia (CML) reported every year.
- In 2001, Novartis introduced Glivec (imatinib mesylate) in India - a wonder drug producing remission in over 90% of CML patients. Novartis priced Glivec at US\$ 2500 for 1 month's treatment to be taken life long to keep the patient alive. In a developing country like India where there is no health insurance for a vast majority of the population, the pricing of Glivec was just out of reach for nearly everyone. Fortunately, almost simultaneously, 9 Indian companies started manufacturing its generic versions priced at an affordable US\$ 180 for 1 month's treatment.
- In 1998, Novartis applied in India for a patent for Glivec and was granted Exclusive Marketing Rights (EMR) in January 2003. As a result Indian courts forbade 6 out of 9 generic producers to market imatinib mesylate.
- As a result: The 3 generic companies could not cover the entire country. CPAA (Cancer Patients Aid Association) and other charitable agencies could not take up the burden of supplying the drug at subsidized rates or free. Thousands of CML patients suffered and many became bankrupt as they tried to buy Glivec and many even died.
- CPAA went to the Supreme Court of India against granting of EMR to Novartis.
- April 2005 - Amendment of India's Patents Act: medicines can now be product patented in India. However, the law stipulates that only true medical innovations will be protected by patents. Section 3(d) specifies that new forms of known substances do not deserve patents.

[Section 3 d says: "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

***Explanation.*—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless**

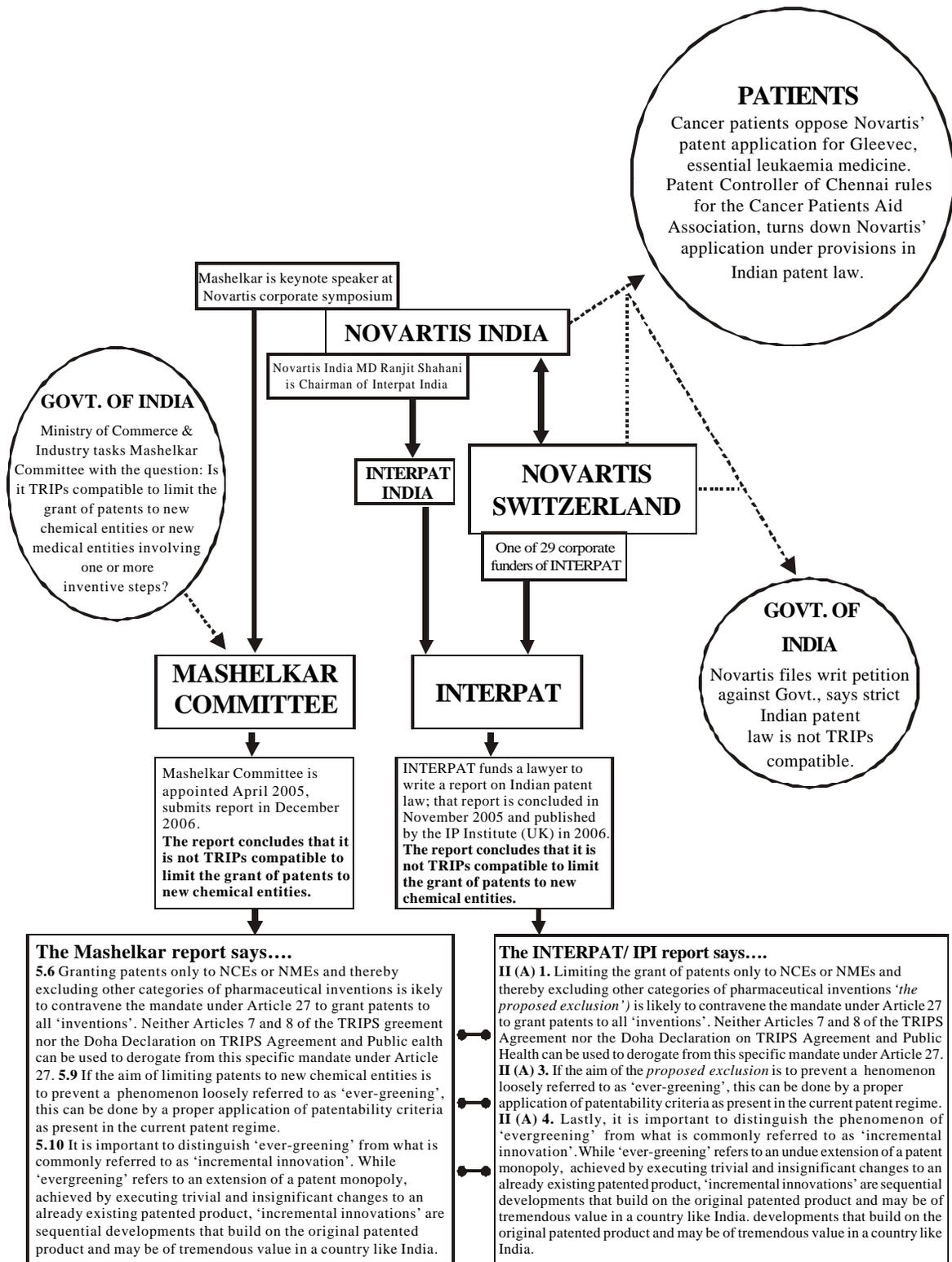
they differ significantly in properties with regard to efficacy. ”]

- Jan. 2006 – Novartis' patent application on Glivec rejected by Indian patent office, on the grounds that it is simply a new form of a known substance.

[The Patent Controller held: The 1993 patent claimed all salts related to the free base that was being patented. Since Glivec was a salt of that free base, and was obtained in the customary manner and was the form that the salt normally exists in, Glivec was a known salt and could not be patented. Since Glivec's salt form was the most thermodynamically stable and also the form that the salt normally assumes, it was obvious. The application only claims a new form of a known substance and in view of Section 3 (d) of the Patent Act must show enhancement of efficacy. The base substance known at the time of application was not imatinib but imatinib mesylate thus Glivec being only a beta-crystalline form of imatinib mesylate was deemed to be only a new form of a known substance and not an enhancement of efficacy. Rejecting Novartis's argument that it was 30% more bio available in rats, the controller held that there had been no enhancement of efficacy. The patent was therefore denied.]

- As a result of the rejection of Novartis' claims, once again generic versions of Glivec were available in the Indian market at affordable prices.
- In May 2006, Novartis appealed against this judgment and also filed a case against the Indian Patent Act. CPAA, MSF, Oxfam & other NGOs launched a global agitation against Novartis. In case Novartis wins both these cases in India, not only will thousands of CML patients die but 100s of life saving drugs currently available at affordable prices will get patent protection and will become unaffordable to patients suffering from life threatening diseases such as TB, AIDS etc. There will be more misery - more poverty, more agony and more deaths at global level, which will be a major catastrophe.
- September 2006 – First hearing of the appeal and challenge. No decision made, but broader hearing set for later date.
- Jan 29 to March 6, 2007 – Hearings in Chennai High Court
- 26 March 2007 onwards - Final hearings on the case in Chennai High Court

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Q&A on Patents in India and the Novartis Case¹

Why do millions of people rely on India for affordable medicines? - What is the relationship between patents and affordable medicines? - Why does India grant patents on drugs now? - Why is Novartis suing the Indian Government? - How is it possible for India to reject a patent that is granted in other countries? - Does India have the right to have this particular patent law? What will happen if Novartis wins the case?

Q: Why do millions of people rely on India for affordable medicines?

A: Drugs produced by companies in India are among the cheapest in the world. That is because until recently, India did not grant patents on medicines. India is one of the few developing countries with production capacity to manufacture quality essential medicines.

By producing cheaper generic versions of drugs that were patented in other countries, India became a key source of affordable essential medicines, such as antiretroviral medicines to treat HIV/AIDS.

Drugs produced in India have been used for the country's domestic market and are also imported by many developing countries that rely on India to provide the medicines needed e.g. to run national AIDS treatment programmes. Over half the medicines currently used for AIDS treatment in developing countries come from India and such medicines are used to treat over 80% of the 80,000 AIDS patients in Médecins Sans Frontières projects today.

Q: What is the relationship between patents and affordable medicines?

A: Patents grant local monopolies to companies who hold them for a certain amount of time. This means that a company that holds a patent on a drug in a particular country can prevent other companies from producing or selling the drug in that country for the duration of the patent's term, which, according to World Trade Organization (WTO) rules is a minimum of 20 years. This in turn allows companies to charge high prices in countries where they hold patents, because there are no competitors in the market.

Competition among producers is the tried and tested way to bring prices down. Competition among generic

manufacturers is what helped bring the cost of AIDS treatment down from \$10,000 per patient per year in 2000 to \$130 per patient per year today.

In the absence of patents, multiple producers compete for a share of the market, driving the price down as low as possible. In addition, having multiple sources helps increase the availability of drugs. Furthermore, the absence of patents in India has helped the development of, for example, three-in-one AIDS medicines and formulations for children.

Q: Why does India grant patents on drugs now?

A: As a WTO member, India has to comply with trade rules set by the WTO. One of these is the Agreement on Trade-related Aspects of Intellectual Property, or TRIPS, which obliges WTO countries to grant patents on technological products, including pharmaceuticals.

To comply with this international obligation, India changed its patent law in 2005 and started to grant patents on medicines. As a result, if patents are granted in the country, Indian generic manufacturers will not be able to produce cheaper generic versions of these medicines, which will have an impact not only in India domestically, but also on other countries that import Indian generics. Only a few new medicines have been patented in India today.

Roche obtained the first pharmaceutical patent in India in March 2006 for a hepatitis C treatment - but this is likely to increase in the future.

Currently, nearly 10,000 medicine patent applications await examination in India. If India begins to grant patents the same way that wealthy countries do - where medicines are routinely protected by several patents covering each small modification - it could mean the end of affordable medicines in developing countries.

Q: Why is Novartis suing the Indian Government?

A: Novartis applied for a patent in India on the cancer drug imatinib mesylate, which the company markets under the brand name Gleevec/Glivec in many countries. The patent was rejected in India in January 2006 on the grounds that the drug was a new form of an old drug, and therefore was not patentable under Indian law.

In other countries where Novartis has obtained a patent, Gleevec is sold at \$2,600 per patient per month. In India,

¹Courtesy: <<http://www.msf.org/msfinternational/>>

generic versions of Gleevec are available for less than \$200 per patient per month. Novartis is therefore trying to have the patent decision overturned so that it can sell Gleevec at the same price in India as in other countries.

Novartis is also trying to challenge the Indian patent law so that patents are as easily granted in India as they are in most other countries.

Q: How is it possible for India to reject a patent that is granted in other countries?

A: There is no such thing as an international or global patent. Patent applications are examined by patent offices in individual countries, and each office deliberates whether a particular drug should be patented or not on the basis of local patent regulations.

Fortunately, India designed its new patent law so that the number of patents granted would be kept to a strict minimum. This was an effort to reward innovation, which is the rationale of the patent system to begin with. The Indian law states that patents should only be granted on medicines that are truly new and innovative.

This means that companies should not be able to obtain patents for drugs that are not really new, such as for combinations or for slightly improved formulations of existing drugs.

This part of the law was specifically targeted at preventing a common practice of drug companies of trying to get patents on insignificant improvements of existing drugs, in order to extend their monopolies on drugs as long as possible.

Novartis is challenging this part of the Indian law, which the company says violates WTO rules.

Q: Does India have the right to have this particular patent law?

A: In 2001, all WTO countries signed the Doha Declaration, which states “that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”

The same declaration allows countries to take measures to protect public health. India’s patent law is based on this declaration. India chose to design a patent law that contains a key public health safeguard, namely the provision that only truly new or innovative drugs should be patented.

Q: Aren’t patents needed to stimulate innovation for new drugs by pharmaceutical companies?

A: An increasing number of studies are showing that while patent protection has increased over the last 15 years, the innovation rate has been falling, with an increase in the number of ‘me-too drugs’ of little or no therapeutic gain. A survey published in April 2005 by *La Revue Prescrire*, concluded that 68 percent of the 3,096 new products approved in France between 1981 and 2004, brought ‘nothing new’ over previously available preparations.

Similarly, the *British Medical Journal* published a study rating barely five percent of all newly-patented drugs in Canada as ‘breakthrough.’

And a breakdown of over one thousand new drugs approved by the US Food and Drug Administration between 1989 and 2000 revealed that over three quarters have no therapeutic benefit over existing products.

Q: What will happen if Novartis wins the case?

A: If Novartis wins the case and succeeds in getting the provision of Indian law changed to resemble patent laws in wealthy countries, patents may be granted in India as broadly as they are in wealthy countries. This will mean that fewer and possibly no generic versions of newer drugs will be able to be produced by Indian manufacturers during the patent terms of at least 20 years, and India will no longer be able to supply much of the developing world with cheap essential medicines.

The example of HIV/AIDS medicines is a good illustration of the problem. Even though older drugs to treat HIV/AIDS have become affordable thanks to generic competition, the availability of newer and improved drugs is crucial, as people become resistant to the drug combinations they take after a certain amount of time and inevitably need to be switched to newer “second-line” drug regimens.

Data from MSF’s project in Khayelitsha, South Africa, illustrates this growing need: 17.4% of people on treatment there for five years have had to switch to a newer drug combination. Yet today, newer drugs are largely still only available from originator companies holding patents, which keeps prices high and availability low.

This is because Indian manufacturers have been reluctant to start producing these newer medicines, as they fear production would have to stop if patents were granted on these drugs in India. This in turn has led to the fact that prices for newer AIDS medicines can be up to 50 times more expensive than older drugs.

Gleevec Updates¹

29th January 2007

The Novartis matter before the Madras High Court in Chennai adjourned today until 15 February for final hearing on all issues, i.e., the challenge to 3(d) of the Patent Act, as well as the challenge to the Patent Controller's order on the merits. The reason being, Novartis wanted to place the Mashelkar committee report on record, which they did only today, and upon which the counsel for the Government of India wanted to seek instructions from government as to its response.

As the order of the patent controller is appealable under the Indian Patent Act, Novartis AG sought to convert the writ petition into an appeal, which was opposed by some of the respondents, as also the Government of India. The issue of whether it can be converted into an appeal, and whether it is within the statutory time limits will be agitated as a preliminary issue on the 15th.

Orders were also passed on the application of the Indian Pharmaceutical Alliance and Indian generic manufacturer, Sun Pharma, to implead them as respondents in the petition challenging 3(d) filed by Novartis AG.

Novartis AG also made it clear that their challenge was two fold: namely, that 3(d) of the Indian Patent Act was not compliant with TRIPS, and on the ground that it violates Article 14 of the Indian Constitution, promoting equality and prohibiting discrimination and arbitrary state statute.

On the issue whether the pleadings were sufficient to make out a claim for Article 14, counsel for Novartis contended that it was sufficiently made out in their rejoinder, and that they would stick by that. Counsel for Novartis also made it clear that they would be dropping the Article 19(1) (g) challenge, which was based on an alleged violation to practice one's business.

Update Feb 15-16, 2007

The Novartis matter resumed today for further oral arguments. At the outset, the Court indicated to the parties that they were inclined to convert the writ petition into an appeal, on the condition that no new

grounds are added in the converted appeal. The CPAA (Cancer Patients Aid Association) and the generic companies agreed to this proposal, but counsel for Novartis indicated that they would seek instruction from the client.

Thereafter, the oral argument by the generic companies and the CPAA began. Starting off was the Additional Solicitor General, Mr. VT Gopalan, appearing for the Union of India and the Patent Controller.

Gopalan responded to two of Novartis' claims: (1) that 3d was arbitrary and (2) that 3d violated TRIPS. He said that the amendment was not arbitrary and in violation of Article 14 because the concepts of "efficacy" and "significant efficacy" are well known and definite in the field. He pointed out that TRIPS allowed flexibilities for member countries. He claimed that TRIPS allowed countries to prevent the abuse of intellectual property rights, including evergreening. He pointed to article 7, 8 and 27 as containing inherent flexibilities.

On constitutional validity, he argued that it is a settled position in India that Parliament cannot be forced to introduce a law. He further pointed out that once a law is enacted by Parliament, courts are bound to administer the law in accordance with the Constitution. There is no decision to the effect that law in violation of an international treaty is void.

On constitutional validity of 3d in light of Article 14, he pointed out that there are only two grounds available for challenging a statute in India: (1) that the law violates the fundamental rights guaranteed in the constitution, or (2) Parliament lacked the authority to enact the law in question. Given that Novartis had failed to state either ground, it had no basis for bringing this issue before the Court.

He then relied on the Statement of Objects and Reasons of the Patents Amendment Act, observing that it mentioned the Doha Declaration. After explaining the mandates of the Doha Declaration to the Court, he contended that the steps to be taken to bring about changes in the patent law had to be member-specific in the context of flexibilities permitted under the TRIPS Agreement.

Gopalan pointed out that the Patent Controller's order denying Novartis a patent on Gleevec were based on other issues besides 3d, including lack of novelty and obviousness. Simply because Novartis had not been granted a patent did not give it a legal basis for

¹ Reproduced in public interest from <http://www.lawyerscollective.org/^amtc/Patent_Oppositions/gleevec/>

challenging the statute. Even assuming that, in this instance, the Patent Controller had arbitrarily applied section 3d, this only provided Novartis with a basis for challenging the Patent Controller's Order, but not the statute itself.

Finally, he contended that the Parliamentary debates that Novartis introduced showing that the legislation discussed the high costs of Glivec and the problem of evergreening was not evidence of Parliament, in bad faith, specifically targeting Novartis.

He also pointed out that the fact that there was such debate in Parliament actually constituted evidence of a legitimate purpose - of Parliament heeding to the will of the people in enacting 3d. As such, this was a perfectly legitimate exercise. Rather than showing irrationality as contended by Novartis, this indicated deliberate decision making in accordance with democratic procedures.

Mr Lakshmikumaran, counsel for Ranbaxy and Hetero, argued that the Court cannot strike down a law on the ground that it violates an international treaty. He showed that the settled law in India was that a treaty does not become law on its own; it can only be used as an interpretive tool used in the case of ambiguity. In the case of a direct conflict between domestic and international law, the domestic law prevails. He distinguished the UK *EOC v. Secretary of State* case that Novartis relied on, ((1994) 1 ER 910), to point out that the issue there whether the Court's jurisdiction to grant a declaration and nothing more.

Addressing Novartis' request for a declaration that section 3d was incompatible with TRIPS, Lakshmikumaran asserted that if the Court did make such a declaration, without granting any further relief, Novartis would use it as ammunition to convince Switzerland to take India to the WTO Dispute Panel. There, if the dispute panel ultimately decided that section 3d was in fact compatible with TRIPS, it would have the effect of placing the Court in an embarrassing situation in which it had been effectively overruled by a foreign body. To avoid this embarrassing situation, he pleaded with the Court not to engage in such a purely academic exercise.

He then pointed out that Novartis's contention that concepts contained in section 3d was unique to India was incorrect. He relied on the EU Directive 2001/83/EC, which contains language virtually identical to 3d in the context of regulatory approval of generic drugs. He used this to point out that the concept of efficacy

was very well known in the field, and certainly very well known to Novartis, which had made several applications for generic forms to be marketed in the European Union, and thus relied on the directive. He further pointed out that they had referred to efficacy in their own specification that was rejected in India.

Lakshmikumaran then argued that there is no basis for claiming that simply because "efficacy" is capable of more than one construction, it is rendered arbitrary. These are relative terms, but well understood by people skilled in the relevant art. He claimed that Parliament deliberately left the term undefined in order to cover the myriad of circumstances in which this concept could be applied. He pointed out that in fact, introducing specific benchmarks of significance or efficacy would in fact render the statute arbitrary.

Finally, he addressed the issue of the Mashelkar Committee report. He pointed out that in view of the fact that the committee had withdrawn the report it may not be necessary to go into the matter. Nevertheless, he argued that the terms of reference were completely different from the issue of the validity of section 3d.

Mr Arvind Datar, counsel for Cipla, again raised the issue that international treaties must be specifically incorporated into Indian law for it to have domestic effect, and that once Parliament has spoken, the Courts must give effect to it, regardless of any international law to the contrary. He asserted that there is always a presumption of constitutionality, and the burden was on Novartis to substantiate its claim. However, he pointed out that Novartis had laid no foundation in its pleadings to make out its claim of arbitrariness.

Datar asserted that 3d complies with TRIPS and was in fact a "golden mean." Referring to varying practices of countries in allowing patenting of discoveries, he argued that there was no universal yardstick of patentability. He argued that though terms such as novelty and obviousness were not defined in the patent law, they were not uncertain and such terms are incapable of being precisely defined. He said that the construction of a patent was the duty of the court. There could be no "one-glove fits all" policy and that the determination of each application should be left to the Patent Controller, but ultimately subject to appeal in the Courts.

Anand Grover, counsel for Cancer Patients Aid Association, reinforced the theory that Novartis could not maintain its request for a declaration of TRIPS non-

compliance. He distinguished the EOC case on the ground that the UK had specifically given domestic effect to the EEC Treaty and that the EEC Treaty itself conferred rights on individuals to enforce its provision and for courts of member countries to enforce them.

He distinguished the EEC Treaty from the TRIPS Agreement, which does not create any rights in favour of individuals or confer any private right of enforcement to individuals. Disputes, if any, have to be between member states as laid down in the Dispute Settlement Understanding, which by its own terms is the exclusive means of resolving disputes. The DSU, Art. 23 prohibits member countries from unilaterally deciding whether the TRIPS Agreement has been complied with.

Grover then compared TRIPS to a prior multilateral treaty, NAFTA, which specifically provides for individuals to enforce the terms of the treaty against a state through arbitration. The drafters of the TRIPS Agreement were aware of such private enforcement procedures but chose not to incorporate them into TRIPS.

He then pointed out Articles 7 and 8 of the TRIPS Agreement as well as two authoritative commentaries on TRIPS (by UNCTAD-ICTSD and WTO-WHO) to highlight to the many inherent flexibilities contained in the TRIPS Agreement. He pointed out that the concepts of novelty, inventive step and industrial application are not defined and that countries are free to determine the means of implementing these requirements, whether through legislative or judicial. He showed that countries may wish to adopt stricter standards for patentability criteria to prevent evergreening.

Anand Grover will continue his arguments tomorrow.

Updates March 5-6, 2007

The Novartis matter resumed today in the Madras High Court. Under the Order of the Chief Justice of the Madras High Court, the appeal of the Patent Controller's order will be heard by the same bench of Justices Balasubramaniam and Prabha Sridevan.

Mr. Soli Sorabjee, counsel for Novartis, commenced his rejoinder arguments relating to Novartis' claim that Section 3d is violative of Art. 14 of the Constitution. He contended that the manner in which the amendment to 3d was introduced, and the fact that India had undertaken a solemn obligation to comply with the TRIPS agreement, introduced an element of irrationality into the legislation, and therefore violated Art. 14. He

further repeated his contention that India's refusal to comply with TRIPS would lead to an erosion of India's credibility internationally.

At this point, Justice Prabha Sridevan interjected and said that she understood the respondents' arguments to say that whether 3d was TRIPS compliant or not was simply not a matter for judicial determination because TRIPS is not part of domestic law.

Sorabjee responded by claiming that the court had to look at the background surrounding the legislation. He claimed that the legislative history showed that Commerce Minister Kamal Nath disagreed with the TRIPS-compliance of 3d, and that while there was uncertainty in the government as to whether 3d was TRIPS compatible, Parliament went ahead and enacted 3d anyway.

Then he argued that the fact that "efficacy" and "significant enhancement" lacked any guidelines made it vague and arbitrary. Responding to the contention that a simple lack of definition did not render a statute invalid, he claimed that while other instances of broad undefined terms had acquired a well-understood judicial understanding, this was not the case with "efficacy" and "significant enhancement," and thus made it vulnerable to varying interpretations that differ from individual to individual.

He pointed to a litany of Indian caselaw to advance the argument that where Parliament delegates unguided powers to the executive branch without laying down any clear legislative policy in the legislation itself, such delegation could be struck down by the courts as an excessive delegation of power.

At this point, Justice Balasubramaniam interjected and said that it was the case of the Respondents that "efficacy" was a concept known to those in the pharmaceutical field, including Novartis, and that the explanation only related to a requirement of significant increase in efficacy. Responding to this, Sorabjee admitted that the meaning of "efficacy" is known and that what was problematic was that section 3(d) did not explain what constituted a "significant enhancement."

At this, Justice Prabha Sridevan observed that it appeared that Novartis' grievance lay in the fact that section 3(d) did not provide a specific percentage for what constitutes "significant enhancement." She said that it could be case that for a headache medicine, a 30% enhancement in efficacy may not amount to an

increase in efficacy but that it could be amount to a significant increase in efficacy for an anti-cancer drug. She said that it would be incorrect to lay down the a specific percentage and that section 3(d) gave leeway to the Patent Controller to allow patentability of new forms of known substances. To this, Sorabjee replied that Novartis was not claiming that a rigid standard be defined.

Sorabjee argued that section 3(d) created an irrational legal fiction of deeming new forms of known substances to be the same substance. He said that he would refer to authorities to cite instances in which irrational legal fictions had been struck down. Sorabjee said that after creating such an irrational fiction, an attempt was made to provide an escape route by introducing the requirement of significant increase in efficacy. He said that it was important to have guidelines which were flexible.

Justice Balasubramaiaim asked how Parliament could possibly anticipate all derivatives of known substances and list them. Responding to this, Sorabjee claimed that it was an irrational legal “fiction” to deem different substance to be the same substance. He argued that this legal “fiction” was arbitrary, and that this arbitrariness was not cured by allowing only certain new forms to be patented.

Admitting that Parliament could not lay down a rigid standard to determine what constituted an increase in efficacy, he argued that neither could Parliament leave section 3(d) without providing any guidance to the Patent Controller. He reiterated that a determination of what constituted a significant increase in efficacy would be a value judgment and that there was no guideline in section 3(d) that would guide the Patent Controller in arriving at this judgment.

To show how arbitrary 3(d) could be, he pointed to the affidavit filed by the Patent Controller, where he stated that a 30% increase in bioavailability “may or may not be statistically significant.” He argued that if even the patent controller did not know what constituted significance, then 3(d) surely was vague and ambiguous.

Mr. Shanti Bhushan, also appearing for Novartis, commenced his argument that 3(d) was incompatible with TRIPS. He claimed that the EU Directive, from which the language of 3(d) was borrowed, related to the drug regulatory review process, and such concepts, as applied to patentability criteria, would result in an absurdity. He claimed that the drug regulatory approval

process generally took place years after a drug was patented, and that the clinical trials necessary to establish efficacy could not possibly be presented as evidence to satisfy the requirements of 3d during the patent examination stage.

At this point, Justices Balasubramaniam and Prabha Sridevan both interjected, observing that while this may be true in some circumstances, it was the case that Novartis actually knew and had data relating to the efficacy of imatinib mesylate during the patent examination stage. Mr. Bhushan admitted that this was the case, but this was only so because of the lag of several years between the filing of the application in the “mailbox” and the examination of the application in 2005. Justice Prabha Sridevan observed that whatever the reason for the lag, if Novartis did in fact have clinical trial data relating to imatinib mesylate’s efficacy, on what basis could Novartis claim that 3d imposed an unreasonable requirement?

Justice Prabha Sridevan also asked what the difference was between “invention” and “discovery.” She asked whether or not it was the case that only inventions needed to be patented, and discoveries did not need to be patented. Viewed in this light, she asked whether 3(d) is not a valid exclusion of all discoveries of new forms except for those with an increase in efficacy. To this, Mr. Bhushan replied that all “discoveries” become patentable “inventions” if such “discoveries” involve an inventive step.

Bhushan then continued with his argument that because section 3(d) imposes requirements above and beyond the basic requirements of novelty, inventive step and industrial application, it was in contravention to Art. 27 of TRIPS. He contended that Articles 7 and 8 provided for flexibilities only with respect to compulsory licensing, which India took advantage of in section 84, et seq of the Patents Act. He further argued that Article 27 only contemplates exclusions from patentability as laid out in Articles 65(4), 70(8), and subsections (2) and (3) of Article 27, and that no further exclusions are allowed under TRIPS. Justice Prabha Sridevan asked whether it was his contention that the exclusions contemplated under 27(2) and (3) formed an exhaustive list of valid exclusions from patentability, to which Bhushan replied in the affirmative.

At the conclusion of the day’s proceedings, Sorabjee indicated that he came to learn of the fact that the Additional Solicitor General, VT Gopalan, intended on filing some additional documents, one of which was

the letter written by Henry Waxman to Novartis asking it to reconsider its position on the case. Sorabjee asked that the documents be filed today, so that Novartis could examine it and initiate contempt of court proceedings against Congressman Waxman.

To this, Grover responded that Novartis should examine its own website on which they were posting comments on the merits of the case, which also amounted to contempt of court.

Bhushan will complete his arguments relating to TRIPS tomorrow, at which point the Respondents will have the opportunity to respond to some of the new arguments that Novartis presented during its rejoinder. We will keep you posted.

Update March 26, 2007

The Novartis matter resumed today in the Madras High Court. Mr. Shanti Bhushan resumed his argument that section 3(d) of the Patents Act was in violation of TRIPS. He reiterated that Art. 1 of TRIPS set minimum standards, and did not allow for member states to go below these minimums. He argued that Art. 27 required all inventions that are new, involve an inventive step, and are capable of industrial applications be patented, and that Art. 27(2) and (3) provided the exhaustive list of exceptions, which India had availed of in Sections 3(b) and 3(i) of the Act.

He then discussed section 2(j) of the Act, which defines “invention” and noted that it only required the three basic criteria for patentability, and that these constituted the only valid grounds for denying a patent.

He then discussed the Doha Declaration, and noted that paragraph 2 of Doha explicitly recognised that TRIPS is a necessary component in providing for access to medicines. Bhushan argued that the enforcement TRIPS was necessary to provide access to medicines, because it was only through the protection of patent rights that the incentive to develop new medicines would be created. He also observed that Doha explicitly reaffirms the TRIPS agreement, while providing for certain flexibilities to promote access to medicines for all. He argued that various sections in the Act that allow for compulsory licensing fully utilized the Doha flexibilities.

At this point, J. Prabha Sridevan interjected to state that the Doha flexibilities were not limited to the use of compulsory licensing mechanisms, and that they provided for a wide range of flexibilities that recognized the sovereignty of member states.

Bhushan responded by admitting that other flexibilities were indicated under Doha, but these flexibilities did not include the freedom to enact 3(d), which was an exclusion from patentability not allowed under TRIPS. He explained that paragraph 5 of Doha indicated what the permissible flexibilities were, and that paragraph 5 discussed the freedom of member states to issue compulsory licenses on any grounds that it deemed appropriate.

He stressed the fact that research and development for new drugs was time consuming and expensive, and that it was critical to provide an incentive for innovation. He stated that it would be better to have the poor wait 20 years for cheaper medicines, while in the meantime providing medicines through voluntary donations than to have section 3(d), under which no new drugs would be developed at all. He asserted that if you don’t have product patent protection, no new medicines would be developed.

Bhushan then discussed the EU directive from which the concepts in 3(d) were borrowed. He made the distinction between drug patenting and drug approval, and argued that it was unreasonable to import the “efficacy” standards used in the drug approval stage into the drug patenting stage. He then pointed to the data exclusivity provision in the EU directive, and argued that even in the drug approval phase, there was a recognition that there was a need to provide incentives to make new drugs. He then discussed various provisions in the Indian Drugs & Cosmetics Act to show that the dossier that a drug company was required to submit for drug approval could not possibly be submitted at the patent examination stage. Bhushan responded to Grover’s earlier argument that Art. 4bis of the Paris Convention allowed for varying patentability criteria across countries. He claimed that all Art. 4bis showed was that applicants were required to file separate applications in individual countries.

In response to Grover’s argument that Art. 27(2) and (3) were not an exhaustive list of valid exclusions, he asserted that such an argument flew in the face of the requirements of TRIPS. He then argued that TRIPS provided for limited flexibilities for countries to define the standards for novelty, inventive step and industrial application, but that such allowable differences were only a matter of degree. Countries, for example could ensure that trivial improvements were not patentable. At this point, J. Sridevan wondered whether “trivial” could be synonymous with “non-significant.”

Bhushan then attempted to discuss the Mashelkar report. At this point, Justice Balasubramaniam remarked that the Mashelkar report had been withdrawn.

Bhushan responded by saying that he simply wanted to rely on some facts contained in the Mashelkar report. Grover and Raman objected to this, saying that if Bhushan wanted to rely on facts, he should introduce it in some other manner and not rely on a report that had since been withdrawn.

Instead of relying on the Mashelkar report, Bhushan asserted that Indian companies were unable to make innovative drugs, and that they were only filing for patents on incremental innovations abroad. At this point, Lakshmikumaran, representing Ranbaxy, objected to Bhushan's vilification of Indian companies in this manner. J. Sridevan then interjected, stating that the excellence or otherwise of Indian companies was not at issue in this case. Bhushan then stated that he would compliment any of the generic companies present in the court if they were able to eradicate cancer or polio in two years.

Bhushan then brought up the Equal Opportunities Commission case, relying on this case to show that the Court had the discretion to issue a declaration that 3(d) was in violation of TRIPS and a High Court, in its jurisdiction under Article 226 of the constitution of India could issue such a declaration. J. Balasubramaniam interjected and pointed out that in that case the international treaty had been incorporated into domestic law and explicitly gave individuals the right of private enforcement. Bhushan attempted to distinguish this by stating that the House of Lords issued a declaration that the U.K. law was inconsistent with the European Convention, not U.K. law.

Post-lunch, Bhushan retracted his reliance on the Equal Opportunities Commission case, saying that it could be distinguished from the present case. He simply reiterated his earlier argument that the powers of the High Court under Article 226 of the Constitution of India are not circumscribed and absent any caselaw to the contrary, a High Court could issue a declaration. He said that the TRIPS Agreement created rights in favour of the Petitioners and that India had contravened their rights by not implementing its obligations and therefore the Petitioners were entitled to a declaration. He then rested his case.

Badshah, counsel appearing for Novartis AG, focused on two aspects which he felt troubled the judges: price of Gleevec and the Doha Declaration. At this J. Prabha Sridevan clarified that price, up to this point, had not been a consideration. Nevertheless, Badshah, proceeded to justify the high price of Gleevec by

discussing the generosity of the Gleevec International Patient Assistance Program. With respect to the Doha Declaration, he argued that para 5 is an actualization of the requirements of para 4 and that the Doha Declaration was fulfilled in other provisions of the patent law.

Badshah then read the main portion of Section 3(d) and the explanation and argued that the explanation expanded the scope of the main portion, which according to him, is not permissible.

The court then adjourned for the day. Badshah will continue his arguments when court reconvenes tomorrow.

Update March 27, 2007

The Novartis matter resumed today. Basha continued with his argument that 3(d) did not provide any guidelines and was therefore arbitrary. He cited judgements to show that where Parliament does not provide guidelines the act can be voided as arbitrary under Art. 14 of the Constitution.

He argued that the decision as to whether there was a significant enhancement in efficacy was left entirely up to the patent controller, and that if the Patent Controller decided in a particular case, it would adversely affect the consumer groups who would not have all the necessary knowledge to challenge the order. He insisted that there should be guidelines either specified by law or by a notification issued by the government or by subordinate legislation.

At this point, J. Balasubramaniam asked how it would be possible for the legislature to determine what enhanced efficacy would be in all situations. Therefore, the law gave the discretion to the patent controller, and if the patent controller made an error, this could be corrected by the appellate courts.

J. Sridevan added that fixing a certain standard for all drugs would result in inequality, as different standard would apply to different drugs.

Basha then again argued that the flexibilities in the Doha Declaration pertained only to compulsory licensing, and did not contemplate or allow 3(d)

VT Gopalan, the Additional Solicitor General appearing for the Government of India and the Patent Controller, introduced caselaw to support his argument that the Court was the final arbiter to determine Parliament's

intent. He argued that the Court could take into consideration all relevant circumstances in determining the objectives of the legislation. He then requested that the Court take note of the international community to section 3d. In this vein, he read aloud certain portions of Congressman Waxman's letter to Novartis discussing the importance of sec. 3(d) in making drugs accessible and affordable, and of the "chilling effect" of Novartis's challenge in encouraging other member states from introducing public health safeguards into their laws. He also introduced the letter from the Members of the European Parliament to support these arguments. He then concluded that this view of the international community reiterated the fact that patentability standards were meant to be member specific, and that 3(d) was in compliance with TRIPS.

He then addressed the issue of Novartis' claim that 3(d) conferred excessive delegation of powers. He argued that the trend in recent times was not to invalidate the delegation of the discretionary power itself, but to challenge the improper exercise of that discretionary power in individual cases. He added that because the function of the Patent Controller was quasi-judicial, in which all parties were given an opportunity to be heard and avenues for appeal existed, these provided sufficient safeguards against the exercise of an abuse of these discretionary powers.

He cited further judgments to support the claim that not all grants of discretionary power is not discriminatory, and that there is no presumption that even where wide powers are granted it will be abused.

He then cited further caselaw supporting the primacy of domestic legislation over international treaty obligations.

At this point, J. Sridevan interjected and said that the primacy of domestic law was no longer in doubt. She asked, given that Novartis claims that section 3(d) is not TRIPS compliant, and that the respondents claim that 3(d) is TRIPS compliant, could the Court express its views on this matter?

Gopalan replied that the Court should not look into the issue at all, and in his view, the matter was not justiciable.

J. Balasubramaniam asked at this point what his response was to Novartis' contention that efficacy could not be made a patentability standard because efficacy was determined during clinical trials. Gopalan replied that he would address this issue during the appeals phase. Then, Lakshmikumaran, appearing for Ranbaxy and Hetero, began his argument by

claiming that paragraph 5 of the Doha Declaration was not exhaustive of the flexibilities discussed in paragraph 4. He noted the language in paragraph 4 discussing the right of members to protect public health, as well as the language in paragraph 5 that discussed flexibilities as including, but not limited to, compulsory licensing. He argued that this language gave member states extra elbow room in taking measures to protect public health, in whatever form.

Lakshmikumaran then responded to Bhushan's argument yesterday about the fact that if patents did not exist, then there would be no research, no medicines, and thus people would die. He pointed out that there in fact was no product patent protection in India until 2005, and yet new drugs were being developed. Bhushan then clarified that his hypothetical concerned a situation in which no product protection existed anywhere.

Lakshmikumaran then pointed out that 3(d) was a valid exercise of the flexibilities available under TRIPS. In response to Bhushan's arguments that Art 27 of TRIPS provided an exhaustive list of exclusions, he read out section 3(a) which disallows the patenting of frivolous applications, and the latter part of section 3(d), which excludes new use, neither of which are expressly provided for in Art. 27. He then argued that section 3(d) only clarified when a patent application became frivolous in line with the basic patentability criteria. He explained that section 3(d) was necessary to stop evergreening, and explained how companies could subsequently patent frivolous modifications to extend patent protection. He argued that this was a case in which Novartis claimed not to understand the concepts of efficacy and significant enhancement of efficacy, and therefore wanted the law struck down. However, he claimed that Novartis was refusing to understand the meaning of efficacy, but that in Europe, Novartis fully understood these concepts and used them to gain marketing approval for many drugs.

He then argued that the language from the European Directive was actually borrowed from pre-existing judge-made law in Europe that had become codified. He showed how Novartis was actually party to the case in which these concepts were litigated to show that Novartis had full understanding of what efficacy meant. The case in which Novartis was involved concerned a "critical dose drug," in which a slight overdose could prove fatal and a slight underdose could prove ineffective. He used this example to show how the concepts of "efficacy" and "significance" could vary from drug to drug, and how Novartis itself was aware of this fact.

He reiterated that the appropriate forum for determining TRIPS compliance was before the DSU, and that any such pronouncement by the Court would only result in embarrassment. Responding to J. Balasubramaniam's earlier question to Gopalan about whether it made sense to require a showing of efficacy at the patentability stage, Lakshmikumaran argued that this was routinely done by patent applicants. He explained that the industrial application requirement imposed a duty upon applicants to show that any given molecule it wanted to patent could at least potentially have some therapeutic efficacy. He claimed that clinical trials would only confirm the substances efficacy, and would prove the safety of the drug. He pointed out that 3(d) excluded the word "safety" that was included in the EC directive for precisely this reason. He argued that guidance in legislation is required only when the terms are not known, but that the terms used in 3(d) were well known to those skilled in the art.

Grover, appearing on behalf of the Cancer Patients Aid Association, began his argument by asserting that Novartis, not being a party to the TRIPS agreement, lacked standing and that the Court lacked jurisdiction to issue a declaration of TRIPS compliance. He brought to the Court's attention cases he had cited earlier to support the argument that in dualist nations, domestic courts had no role to play if a country failed to abide by its international obligations, unless the treaty expressly provided for private rights of enforcement.

He then reiterated his argument that Art. 27 was not exhaustive and pointed to various provisions in section 3 of the act that were not expressly provided for in 27. He then pointed to authorities to show that TRIPS flexibilities extended to setting stricter standards for patentability by defining the basic criteria of patentability as it saw fit. He pointed to the CIPIH report, which approvingly cited section 3(d) of the Act as a valid exercise of TRIPS flexibilities to prevent evergreening. He then introduced Novartis' own slide presentation on salt selection, in which Novartis acknowledged the usefulness of subsequent patents on salts and polymorphs to extend patent protection.

He then distinguished the caselaw that Novartis had cited regarding excessive delegation, and pointed out that none of these cases applied to the case at hand, because none of the cases dealt with the validity of the grant of quasi-judicial discretionary power. He argued that the inherent safeguards in the grant of quasi-judicial power i.e., fair hearing, reasoned decision, and opportunity to appeal was sufficient to check the abuse of such powers.

He then argued that the explanation to section 3(d) actually provided the further guidance to the patent controller in two ways: to show what new forms of known substances are, and to explain that "significant enhancement of efficacy" could be shown by a showing of a "significant difference in properties with regard to efficacy."

Bharat Raman, appearing for Natco, argued that Novartis, throughout the prosecution of the application, had full knowledge of what was meant by efficacy and enhancement of efficacy. He cited to Novartis' own replies to the patent oppositions in which Novartis had argued that the beta-crystal form was a significant enhancement over the free base. Raman argued that it was only because Novartis had failed before the patent controller that they were now claiming that they were ignorant of the meaning of these concepts.

He cited to further caselaw to show that it was precisely the duty of the Court to give meaning to terms in legislation. In this vein, he compared section 3(d) to a new born baby, and implored the Court to give it time to grow.

He further argued that there was nothing inappropriate in borrowing concepts contained in one legislation for use in another body of law. He cited to the old Patents Act, 1970, which borrowed the concept of "drug" from the Drugs and Cosmetics Act.

Responding to Novartis' argument that its novelty could be possibly lost if it were required to disclose test data to obtain a patent, Raman referred the judges to section 30 of the Act. This provision protects communications made by an applicant to the government in furtherance of an investigation of the invention.

The matter was adjourned until tomorrow.

Update March 28, 2007

The Novartis matter resumed today. Raman continued his argument that it was fully within the power of Parliament to incorporate external statutes and treaties by reference or by specific incorporation. He cited to Rule 23 of the Patents Rules, which expressly incorporate by reference the procedures laid down under the Patent Cooperation Treaty. He then argued that Parliament, if it so chose, could also have incorporated by reference the TRIPS agreement. However, Parliament chose not to do so, choosing instead to exercise the various flexibilities available to it.

He then addressed Sorabjee's argument that section 3(d) impermissibly created a legal fiction to state that different substances be considered the same substance. He first reiterated his position that 3(d) did not create any fiction at all. He then argued that even if a legal fiction was created, it was entirely permissible for Parliament to do so. To support his argument, he cited to an Indian judgment that expressly recognised the power of Parliament to presume the existence of facts that may not exist.

Raman then argued that the Court had no power to grant Novartis the declaration that it was seeking. He argued that the scope of Art. 226 of the Constitution, which confers powers upon the High Courts of India, was limited to the grant of a limited class of writs, and the only form of declaratory relief that the High Court could grant was where fundamental rights had been breached. Because patent rights are not fundamental rights recognised under the Constitution, the Court lacked power to grant such a declaration. He further argued that for the sake of avoiding an unnecessary conflict of laws, the Court should refrain from issuing a declaration. He warned of a danger of embarrassment should conflicting determinations on the TRIPS-compliance of 3(d) between the Court and the WTO result.

He then argued that the scope of permissible discretion depended upon whether such powers touched upon fundamental rights. He argued that where the delegated powers did not touch upon such rights, then the degree of latitude under the law was far greater.

He then responded to Novartis' argument that compulsory licensing was exhaustive of India's flexibilities under TRIPS. He denied that such mechanisms were an exercise of TRIPS flexibilities, as compulsory licensing provision had existed in Indian patent law since 1911. During the entire time that compulsory licensing existed under Indian law, he pointed out that only one compulsory license had been granted in India. Even in this one instance, by the time the compulsory license had been fully litigated on appeal, according to Raman, only fifteen minutes of the patent term was left. Thus, the only compulsory license in Indian history existed for only 15 minutes. Therefore, compulsory licensing mechanisms could not be counted on as the only measure to guarantee access to medicines.

He then questioned Novartis' contention that efficacy could not be measured at the patent examination stage. He pointed out that section 3(d) only deals with new

forms of already known substances. He claimed that the efficacy of the existing substance was known, and that the applicant only had to show that its new form improved upon the known efficacy. Rather than posing an unreasonable burden, he showed that several patents on new forms of known substances had already been granted in India under section 3(d).

At this point, J. Sridevan asked whether 3(d) allowed patenting of certain discoveries, which are otherwise not patentable. To this, Raman replied in the affirmative.

Raman then cited caselaw to support the proposition that in legislation relating to economic policy matters as opposed to fundamental rights, greater deference was owed to Parliament because laws relating to economic matters are based on trial and error method and cannot provide for all possible situations. He added that possibility of abuse could not be a ground for striking down a law. He then cited to a decision delivered by J. Sridevan, where it had been held that vagueness in a law, by itself, was not a sufficient ground to strike it down. On the contrary, a law must work and must be interpreted to work.

Bhushan then commenced a brief response to the arguments. At the outset, he clarified that he was not going to deal with the arguments relating to constitutional validity of section 3(d).

He said that the main part of section 3(d) did not concern them because a salt of a substance is not a new form of the substance and is therefore a new substance. He said that Novartis was concerned about the explanation to section 3(d) which considers new substances, such as salts of known substances, to be the same substance.

Responding to the letter addressed by Congressman Waxman to Novartis that was brought on record yesterday, Bhushan said that Congressman Waxman's concern was about the impact of section 3(d) on the availability of medicines for the poor in India and in other countries. He said that Novartis had already pointed out the provisions relating to compulsory licensing, the emergency powers of the Central Government to dispense with the 3-year waiting period for issuing a compulsory licence, and Novartis' Glivec International Patient Assistance Programme, which would address these concerns. He added that it was merely the opinion of Congressman Waxman to which he was entitled.

Bhushan then addressed the slide presentation authored by an employee of Novartis, which Grover

had brought on record to show how salt forms and polymorphs were used to extend patent life. He urged that the patent term extension granted to pharmaceutical companies under the US law was a legal extension of patent life designed to compensate for time lost during the drug regulatory approval process. At this point, J. Sridevan clarified that Grover had not objected to the patent term restoration available to companies under the US law, but had pointed out that Novartis itself was aware that salts and polymorphs could be used to extend patent life. [A copy of the slides will be made available shortly on our website.]

On the issue of the declaratory relief, Bhushan argued that Article 226 of the Constitution of India conferred broad powers to the High Courts and it was not limited to the specific writs that Raman had enumerated. He claimed that it was in the court's discretion to issue such a declaration, especially to an affected party such as Novartis. He claimed that it would be preferable for Indian courts to determine the TRIPs compatibility of section 3(d) so that Parliament could rectify its error, if it so desired, and therefore save itself the indignity of being taken to the WTO Dispute Panel.

At this point, J. Balasubramaniam referred to the two US judgments that Grover had cited, which clearly held that private persons had no standing to challenge non-compliance with an international obligation incurred by States alone. Bhushan replied that the obligations incurred by States were for the benefit of private parties, patentees in this instance, and that therefore Novartis had standing as an affected party. J. Balasubramaniam asked him why Novartis could not move its Government (Switzerland) to take up this issue. Bhushan responded that it was asking the State (India), of which the Indian judiciary was a part, to determine this issue.

Bhushan then read out the portion of the CIPIH Report dealing with incremental innovations and urged that incremental innovations should not be confused with evergreening. He added that incremental innovations were good for society and that what should be disallowed is patenting of minor improvements, which result in evergreening.

Bhushan claimed that the Respondents had conceded that efficacy need not be proved by clinical trials alone. According to him, as long as other methods to prove efficacy were acceptable, he had no quarrel.

Mr. Anil Mishra, holding counsel for Lakshmikumaran (Ranbaxy and Hetero) clarified that the Respondents

had made no such concession and that, in this particular case, Novartis could have presented data from human trials to prove efficacy.

With this, the arguments in the 3(d) challenge came to a close.

Bhushan began the arguments in the appeal against the patent controller's decision by reading out relevant portions of the Patents Act and the patent controller's order.

He summarised that the grounds for oppositions that were filed by five parties were novelty, non-obviousness, section 3(d) and wrong claiming of priority date.

In 1998, Novartis filed the application for the β -crystalline form of imatinib mesylate as a convention application claiming priority from a 1997 patent application filed in Switzerland. At that time, the Government of India had not declared Switzerland as a "convention country". (Explanation: A "convention application" allows patent applicants to file a patent application within 12 months of the first filing in a convention country. Indian law, in 1998, required the government to declare which countries would be treated as convention countries. After Novartis filed the application, the government of India declared Switzerland to be a convention country. Subsequently, in 2005, the patent law was changed so that India presumed all countries to be "convention countries" and only those explicitly declared not to be convention countries were excluded.) This had formed one of the grounds on which the Patent Controller had rejected Novartis' application. Bhushan urged that the law that would apply was the law that existed at the time the patent application was examined, i.e 2005. Therefore, Novartis could rightly claim priority from the Switzerland application. He added that even a wrong claiming of priority would not be fatal to Novartis' application.

Moving on to the application of section 3(d) by the patent controller to Novartis' application, Bhushan relied on documents to explain the meanings of "bioavailability" and "bioequivalence". At this point, Mr. Anil Mishra (appearing for Ranbaxy and Hetero) informed the judges that it should be clarified that Novartis could not produce additional evidence that it had not produced before the patent controller. J. Balasubramaniam agreed that they would only look at the evidence that was produced before the Patent

Controller. Bhushan said that they would rely on certain technical literature, of which the court could take note of even if it had not been produced before the patent controller. J. Balasubramaniam agreed to let Bhushan cite the documents but allowed the Respondents the right to object to the documents that Novartis relied on.

Bhushan then referred to documents showing that in approving generic medicinal products, bioequivalence range of -20% to +25% were acceptable as equivalent products. He then cited an article discussing the narrow therapeutic index of certain antiarrhythmic drugs in which administering the exact dosage was critical.

At this point, J. Balasubramaniam asked why Bhushan was discussing antiarrhythmic drugs in the context of the Glivec case. Bhushan explained that achieving the right dosage was critical and that critical to this was the bioavailability of a drug. He urged that improved bioavailability would enable administration of smaller dosages, which would reduce toxic effects. He said that because of this, even a 5% difference in bioavailability would be significant.

Bhushan referred the judges to an expert affidavit produced by Novartis to show that the β -crystalline form of imatinib mesylate was 30% more bioavailable than imatinib free base. He said that Novartis had expended huge amounts for research to determine the appropriate salt from thousands of candidates and that the choice of the ideal salt form was a valid selection patent. He further urged that this amounted to an inventive step. The second step of invention was to find the β -crystalline form of imatinib mesylate.

J. Balasubramaniam questioned if the patent controller had accepted the affidavit, to which Bhushan replied that the patent controller had accepted the affidavit but had ruled that a 30% increase in bioavailability was not significant. Noting that the 30% improvement in bioavailability was over the free base, J. Balasubramaniam asked if a 30% increase over the free base would result in a significant improvement if the bioavailability of the free base was only 20%. Bhushan replied that even if the dose could be reduced by 1%, the 1% difference would be significant in case of toxic drugs, such as drugs used to treat cancer.

At this point, J. Sridevan noted that the EU Directive relating to approval of medicinal products from which the language of section 3(d) was borrowed, related to both safety and efficacy, but that 3(d) had

conspicuously left out safety. She asked if it were not the case that toxicity related more to the issue of safety than efficacy. Bhushan replied that efficacy and safety were correlated and that it was of no use if a company were to obtain a patent for a drug that, though more efficacious, was so toxic that it could not be administered to humans.

Bhushan then referred the judges to the pharmacokinetics data from a study conducted by Novartis on rats to show the difference in bioavailability. J. Balasubramaniam sought a clarification of terms such as t_{max} and AUC. Bhushan said that he would seek instructions from his clients and explain these terms tomorrow.

Bhushan cited to an affidavit by Manley, a Novartis employee, to show that the β -form was superior to the α -form because it was more thermodynamically stable, had better flow properties and was less hygroscopic. He said that even these properties could amount to an increase in efficacy.

He referred to a paper which acknowledged the efficacy of β -crystalline form of imatinib mesylate over other treatments.

Bhushan then said that on the question of interpretation of section 3(d) in this particular case, he would urge that the term "mere" would have to be given meaning. He urged that in cases, such as the present where an inventive step was involved, it would no longer be a mere discovery and section 3(d) would not apply. He said that if section 3(d) was given this meaning, it would be perfectly TRIPS-compliant.

Bhushan then moved on to the issues of anticipation and non-obviousness. He read out portions of the 1993 US basic patent for imatinib which claimed a patent for imatinib and its pharmaceutically acceptable salts, including mesylate. He claimed that the 1993 patent contemplated thousands of different possible salts and that the selection of one with beneficial properties was a valid selection patent. J. Sridevan asked what was meant by the statement in the 1993 US patent that due to the close relation between the free base and the salts, any reference in the 1993 US patent to the free base should be considered to include all salt form. Bhushan replied that this statement was inserted to claim all possible salts and thus prevent others from infringing its patent.

Bhushan reiterated that unless selection patents were recognised, no one would invest in research and development that results in the final drug form.

The matter was adjourned until tomorrow.

Update March 29, 2007

The Novartis appeal resumed today. Shanti Bhushan continued his argument that the β -crystalline form of imatinib mesylate resulted in an enhanced efficacy over the free base. He pointed to the study conducted by Novartis on rats that allegedly showed a 30% increase in bioavailability of β -crystal form of imatinib mesylate over the free base. At this point, J. Balasubramaniam observed that this study had been conducted on rats. He asked what conclusions we could draw from a study conducted on rats.

Bhushan replied that rats, humans, and monkeys are warm-blooded animals, and that one could assume that an increased bioavailability in rats could also have a similar effect on humans.

Bhushan argued that the compound described in the current patent application represented a two-step improvement over the prior art:

1. The selection of the mesylate salt amongst what he alleged were “thousands” of possible salts disclosed in the 1993 patent (US 5,521,184) that had claimed imatinib and “all pharmaceutically acceptable salts thereof”; and

2. The creation of the β -crystalline form of the mesylate salt. He pointed out that the generic companies were free to manufacture any of the “thousands and thousands” of other possible salts; and that it was indicative of Novartis’ inventiveness that all other generic companies only wanted to copy this particular form of imatinib.

In attempting to distinguish between incremental innovation and evergreening, Bhushan claimed that if a salt form did not improve the drug, then it would admittedly be evergreening, but where a salt did improve the drug, then it could not be considered evergreening.

Bhushan then cited to a series of cases (the table of cases cited will be made available on our website) relating to selection patents to argue that Novartis’ selection of the mesylate salt, with its specially beneficial properties, from “tens of thousands” of possible salts. Bhushan argued that the essential holding of these cases was that where a prior art reference discloses a large number of possible permutations, an applicant who was able to identify a sub-class of these that possess a characteristic that

was “significantly more advantageous” than the others was entitled to a selection patent.

At this point, J. Sridevan asked whether the requirement of showing significant advantageousness was similar to showing a significant enhancement of efficacy under section 3(d). J. Sridevan asked Bhushan whether if selection patents are allowed, wouldn’t 3(d) be equally valid? To this, Bhushan replied in the affirmative.

Bhushan then introduced some documents: an article on solid state pharmaceutical chemistry and two entries printed from the Wikipedia website, to show the steps in drug development and to show the complexities involved in salt selection and polymorph discovery. At this point, several counsel objected to Bhushan’s reliance on Wikipedia.

Bhushan then read the relevant portions from the Indian application to show the potential use of imatinib to treat various disorders, including CML, restenosis, and thrombosis. He also read the portion in the Indian application that states: “It goes without saying that the indicated inhibitory and pharmacological effects are also found in the free base...or other salts thereof.” He further read the portion which admitted that the activity of the mesylate salt was described in a 1996 publication.

He then went through the USPTO prosecution history and pointed out that in the USPTO as well, the patent examiner had initially rejected the subject application on the grounds of anticipation and obviousness. He pointed out that the USPTO Appeals Board reversed the patent examiner’s rejection, holding that the patent examiner had not relied on any data to show that the 1993 patent “inherently disclosed” the β -crystalline mesylate salt.

In response to test data that Natco had submitted during the pre-grant opposition phase which showed that the β -crystalline form was inherently formed when the mesylate salt was prepared, Bhushan attempted to introduce an expert affidavit dated April 2006, four months after the Patent Controller’s Order. At this point, Grover objected on the grounds that under the Indian Code of Civil Procedure, Novartis could not introduce evidence that was not before the Patent Controller unless it could show that despite due diligence, it could not have made such evidence available to the Patent Controller. Grover argued that Novartis had ample opportunity to, and in fact did, reply to the tests that Natco had submitted, and that Novartis was now barred from introducing new facts

before the Court. The justices replied that the objections had been noted and that the respondents could argue this at the time of response.

Bhushan then took the Court through the data submitted by Natco, which were submitted by two reputed institutes: the Indian Institute of Technology (Delhi) and the Indian Institute of Chemical Technology (Hyderabad), which had confirmed that in making the mesylate salt of imatinib in a variety of conditions, the β -crystal form was invariably produced. Bhushan claimed that this data was entirely irrelevant, as Natco had allegedly supplied the institutes with the β -crystalline form. Moreover Bhushan claimed that the data was irrelevant because these institutes were merely reproducing the mesylate salt by combining methane sulfonic acid with imatinib, which would obviously result in the mesylate salt. He asserted that this proved nothing, and that the true test to show that Novartis' patent application was without merit would be for Natco to have supplied the institutes with nothing more than the '93 patent, and asked them to come up with a suitable salt with equivalent or better bioavailability as the mesylate salt.

He then started to go through the affidavit that had been objected to, when J. Sridevan interjected and stated that given the tenor of the affidavit, which implied that IIT and IICT had inadequately performed these tests without taking proper precautions, she felt that it was unfair for Novartis to rely on such an affidavit. She stated that ruling on this would require the Court to question the integrity of these institutes. Bhushan conceded this point.

He then relied on another affidavit that had been made available to the Patent Controller which stated that it was unsurprising that IIT and IICT could come up with nothing but the β -crystal form, as Natco had never had access to the α -crystal form, and that the samples that Natco had supplied to these institutions would have inevitably been contaminated with β -crystal seeds, thus invariably resulting in the creation of the β -crystalline form.

Bhushan then relied on some orders passed in infringement proceedings against Natco in the UK, in which Natco had agreed not to market or sell the β -crystalline form because it would infringe Novartis' '93 patent.

At this point, the Court adjourned for the day. Bhushan will continue his arguments tomorrow.

Update March 30, 2007

The Novartis appeal resumed today, with Bhushan resuming his critique of the IIT and IICT studies that were submitted by Natco to show that the β -crystalline form invariably formed when the mesylate salt was produced. He pointed to Example 1 of the Indian specification, which showed how to create the α -crystal form. He then showed that one of the experiments conducted by IICT was essentially identical to the example cited in the Indian specification. He concluded from this that the imatinib free base that Natco had supplied to IICT must have been contaminated with β -crystal seeds, thus inevitably resulting in the β -crystal. He alleged that Natco must have reverse engineered the imatinib free base from the β -crystal form, thus resulting in the contamination.

In this context, he again discussed an affidavit submitted by Novartis' expert, who concluded that the β -crystal form must have been attained through contamination.

Bhushan then pointed to Hetero's pending application for the amorphous form of imatinib mesylate, and claimed that this proved that, contrary to Natco's allegations, the β -crystalline form is not obtained invariably. He also pointed to Natco's own admissions which showed that Natco, Cipla and other companies had applied for and received marketing approval on the α -form of imatinib mesylate. He further cited to other references to show that forms other than the β -form were known and being used by the generic companies.

Bhushan then read out the Order of the Patent Controller in which he dealt with Novartis' argument that it was entitled to a selection patent, to show that the Controller had not applied his mind on the issue of selection patents. Bhushan pointed out that Novartis had specifically raised the issue of selection patents, but that the issue was never dealt with in the Order.

Bhushan then argued that on the issue of claiming wrong priority, first that the relevant law to be applied in this case was the current law, which presumes all countries to be convention countries unless otherwise specified. Even if wrong priority had been claimed, Bhushan argued that this was not a ground for rejection, because this would only serve to change the priority date to July 1998. He claimed that nothing had been published between 1997 and 1998 that would affect the patentability of the subject application.

In solidarity,

The Lawyers Collective HIV/AIDS Unit Team
Anand, Chan, Julie, Asha

Letter to Novartis Counsel Shanti Bhushan from AIDAN

Tuesday, 13 March 2007

Dear Mr. Bhushan,

Why are we writing to you?

We are writing to you on an issue which is of critical concern, both to present and future generations of Indians, i.e., of access to essential medicines, which are available and affordable. We are writing to you particularly as you have served with distinction, as the Law Minister and otherwise, to represent issues of public interest in the highest court of this land and you have the reputation of being a public-spirited person.

Our people suffer one of the highest burdens of diseases in the world: every third malnourished child lives in India, we have the largest number of patients of tuberculosis and diabetes in the world, and the second highest number of patients with HIV disease. The list could go on. And here is a paradox. In spite of having one of the largest pharmaceutical sectors in the world providing drugs at the cheapest prices in the world, we have also the world's largest population without access to essential medicines. Medicines are neither available in the public health system nor affordable in the private health system. Illness and healthcare costs are now one of the biggest reasons for perpetuation of poverty.

Novartis and Imatinib Mesylate

It has come to our notice that you have decided to represent Novartis in a case, the outcome of which will not only determine whether thousands of Indians with a particular type of cancer will live or die, but also all other diseases. This is because Novartis has not only challenged the order of the Patent Controller, but also section 3(d) of the Patents Act 1970, which ensures that evergreening does not take place and thereby allows competition and keeps prices of drugs low. The outcome of this case shall also determine whether people, not only in India, but all over the world, who depend on the ability of Indian companies' to provide lower priced generic medicines shall die for want of affordable medicines. Indian generic companies supply 67% of the drugs in the developing world.

Novartis is a multinational company which was one of the many which fought the South African government which was doing its duty and trying to save the lives of millions of HIV affected in South Africa by making drugs available to them. The case was precipitated by the drug companies refusal to offer drugs at lower prices and the dramatic offer of an Indian company to do so at only 3% of the price charged by the multinationals.

High drug prices do not reflect merely the high costs of R&D. Much of the basic research work that underlies any new drug development occurs in public funded institutions like the National Institutes of Health. It was so even with imatinib mesylate the drug which is at the centre of this case, which would never have been developed but for work on the chromosomal abnormality underlying chronic myeloid leukaemia which was done at public expense. Even the demonstration of the spectacular efficacy of this drug specifically in chronic myeloid leukaemia was due to the initiative and persistence of Dr. Druker of the Oregon Institute of Health Sciences.

How Prices are Determined?

Pharma companies spend more on advertising and promotion, and earn more profits every year than they spend on R&D. Finally, even in drugs which have long gone out of patent, and whose development costs have long been recovered drug companies charge artificially high prices. In fact the lack of connection between drug prices and R&D costs were admitted by no less than the CEO of one of the leading Pharma companies in the world, Merck, who said "Price of medicines is not determined by their research costs. Instead it is determined by their value in preventing and treating disease. Whether Merck spends \$ 500 million or \$ 1 billion on developing a medicine, it is the doctor, the patient, and those paying for our medicines, who will determine their true value." Can Indian patients decide then that the true value of imatinib mesylate is Rs.8000 per month rather than Rs. 120,000 being charged by Novartis?

The drug industry's position on both patents and price regulation is completely in line with concern for ever-increasing profit and lack of concern for the human implications of this unstinted greed for profit. A great poet of the last century, Pablo Neruda said while speaking of the poet's duty, "I determined that the posture within the community and before life should be in a humble way of taking sides."

On whose side are you?

On whose side will you stand Mr. Bhushan? On the side of your people and their distress or the balance sheet of a multinational company? Is the cause you now represent, in line with what you championed not so remotely in the past? Another illustrious lawyer of this land stood on the side on a company responsible for one of the worst industrial disasters in history for which thousands have paid the price. We appeal to you to stop representing Novartis in this vital case and assure you that your example shall long be remembered by both lawyers and the people of this vast and suffering nation. In our appeal we are only reminding you of the words of one of the most illustrious lawyers this country has produced, "There is a higher court than courts of justice and that is the court of conscience. It supersedes all other courts." The lawyer was M.K. Gandhi.

Sd/- Dr. Mira Shiva, Dr. Anant Phadke, Dr. Sathyamala C. , Mr. S. Srinivasan, Dr. Anurag Bhargava, Mr. Gopakumar, Mr. Prasanna Saligram, Mr. Siddharth Narain, Mr. Vinod Bhanu, Dr. Gopal Dabade, Mr. Naveen Thomas, Ms. Priya Pillai, Ms. Jaya Nair, Udaan, Mr. Loon Gangte, Mr. Naresh Yadav, Mr. K. K. Abraham, Ms. Rukmini Pillai

(A similar letter has been sent to the other Novartis counsel, Soli Sorabjee.)

Assisted Reproductive Technologies: Implications on Women's Lives

-Sama Resource Group for Women & Health*

Assisted Reproductive Technologies (ARTs) have been fast gaining ground since the birth of the world's first 'test tube' baby, Louise Brown.¹ The advent of these technologies in India may have been started in the same year, as Dr. Subhas Mukherjee claimed to be the lab parent of Durga, India's first and the world's second IVF baby. However, due to lack of proper scientific documentation and peer review, his efforts were not recognized.² So, it was on August 6, 1986, that India's first 'scientifically documented' IVF baby, Harsha, was born through the collaborative efforts of the Indian Council of Medical Research's Institute for Research in Reproduction (IRR) and the King Edwards Memorial hospital (KEM), Mumbai.³

Although research and promotion of ARTs was undertaken in India as a government/public sector initiative, it soon fed into the private health sector and has since then flourished as a private enterprise. The potential market for ARTs in India has been on a steady rise ever since its introduction, and is currently estimated conservatively at 25,000 crores⁴. The clinics providing infertility 'treatment' have also mushroomed all over the country, including smaller towns and rural areas. Besides an increase in the numbers of Indian 'childless' couples going in for these procedures, there is also a massive influx of people coming in from foreign countries to access these procedures in India. This increase in medical tourism can be attributed to the cost effectiveness of 'treatment' in India as well as lax regulatory mechanisms of the ART industry here.

Infertility and the ART Industry

*"But why can't I have a child? Maybe I have done something terrible in my life and now God is testing us. ... there must be some shortcomings in me only and that is why I am not conceiving."⁵
—a woman undergoing ART procedure*

Advances in medical science, including ARTs, reflect the existing social context and incorporate social arrangements and power relations. In a patriarchal society such as India's, child bearing and motherhood are glorified, albeit only for married women. Failure to perform this role for whatever reason, makes the couple, especially the woman, vulnerable to stigmatisation, social ridicule and even ostracism. Often, this social pressure is internalised, giving rise to intense feelings of guilt and shame on the part of the couple for not being able to perform the "normal" and "expected" role. What is striking, however, is that although infertility

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affects both men and women, it is usually the woman who is blamed for childlessness. This reasoning emerges from a patriarchal belief system that treats reproduction as a woman's responsibility. It is in this overtly patriarchal social context that infertility threatens the social status of a woman, both in the family and the community and sometimes even in her marriage. Since motherhood is central to the social construction of womanhood, childlessness is a social crisis that cheats childless women of their fundamental identity. Given this epitomising of motherhood, one can understand why women who fail to bear a child often subject themselves again and again to the long drawn and often perilous procedures of ARTs rather than adopt a child.

Thus, ARTs circumnavigate the space between the traditional and the modern, using both to their advantage. The ART industry reinforces these traditional patriarchal norms rather than really challenging or subverting them. It propagates the myth of an infertility epidemic, although there is no data to support the claim that infertility is (f)actually on the rise. Still this claim has taken hold in popular perception, and is fervently propagated by the media and the medical establishment. This medicalisation of childlessness, its transformation into a disease, is part of the larger politics behind the commercialization of both fertility and infertility. Once the disease of infertility has been created, ARTs come forward to provide a treatment. However, it is important to note that although ARTs are fraught with the language of disease, they cannot address the underlying causes of infertility such as pollution, workplace stress, or untreated pelvic inflammatory diseases. At best, they may provide an individual solution to a deeper rooted problem.

The end result is the further subjugation of women, by firmly casting them in the role not only as "child bearers", but as bearers of sons, who will then propagate the *vansh*, i.e. the family lineage. In this scenario, infertility becomes a stigma and an epidemic, leading to ostracism of the childless women. Moreover, the ART industry has also created new commodities and economic equations, which will surely worsen the exploitation of women who already face oppressions of various kinds, social and economic.

The Study

From 2004 to 2006, Sama⁶ conducted a qualitative study on the various implications - medical, social and ethical

- of ARTs on the lives of women in the Indian context⁷. The study was done in Delhi, Mumbai and Hyderabad and comprised interactions with the providers of ARTs as well as women undergoing these procedures. The research was guided by the premise that the proliferation of ARTs in a patriarchal social scenario makes women doubly disadvantaged; they must suffer the burdens of the prevailing patriarchal hegemony and those created by the medicalisation of everyday life. This premise was based on the "...historical fact that technological innovations within exploitative and unequal relationships lead to an intensification, not attenuation, of inequality, and to further exploitation of the groups concerned"⁸.

The data was primarily collected through detailed, informal and semi-structured interviews with the providers of these technologies, and with women undergoing these technologies. Supplementary interviews were conducted with ICMR officials and feminists and health activists from different progressive movements in India. A review was done of existing literature on ARTs in various publications and publicity material. A critical review of the ICMR guidelines was also undertaken in order to gauge legal regulatory mechanisms in place.

A total of 23 providers were interviewed. Twenty-five women were interviewed, who were either going through IUI and IVF, or had been advised these procedures.

Findings

Since the study group was small and the limitations many, we are wary of making any generalizations. However, despite these constraints, this study highlights various implications that the advancement of ARTs in India may have for women.

This paper is based on the research initiative, and draws on some of the findings encountered during the research and arranged in the following order:

a. the nature of information (further subdivided as information and counselling, side effects and complications, and informed consent), b. the perceived success of the techniques,

Each section is given according to the responses of providers and of women undergoing these procedures

Nature of Information and Counselling

Any medical treatment entails disclosure by the doctor of all the information relating to the treatment. This includes the treatment's potential side effects and complications, its efficacy, as well as existing alternative

treatment. Counselling is equally important, especially because of the emotional stress associated with infertility. It is also important to prepare couples for the possibility of repeated failures to conceive, and the risk of various side effects and complications.

Providers' Perspective

Only 12 of 23 providers responded to a query on the type of information and counselling given to women undergoing these procedures. The information was mostly about a few side effects (mainly excluding the more serious and significant ones like ovarian twisting, for example), with some details of the procedures, figures on success rates, and costs. Counselling seems to have rarely been undertaken, and that too only for couples with "special" cases like where "both the husband and wife have thalassaemia" or when donor sperms or eggs would be used.

This reinforces one's impression that the information provided is primarily piecemeal and inadequate. In fact, only one provider claimed to give complete details along all the criteria mentioned above. Doctors seem to use the hierarchical patient-doctor relationship to control women's access to knowledge. They believe that they are not bound to impart comprehensive information. In this scenario, it is difficult for women either to have a complete picture of the process they are embarking upon or to be part of the decision-making process.

Women on Information and Counselling Provided

Ten of the 25 women interviewed said they did not know much about the treatment as the doctor was always too busy or they were hesitant to ask. Eight said they had some information on the procedures' success rates only. One woman said that she was categorically told that there would be no side effects or complications.

Though some of the women expressed their dissatisfaction with the lack of information, others felt that the doctor might have told them had they asked, but often hesitated to do so for fear of offending him/her.

Information Regarding Side-Effects and Complications of ARTs

Providers' Perspective

Nineteen of the 23 providers spoke about the side effects and complications of the drugs and procedures. In general, they said that there were no major health risks. Some did name some risks, when they were probed, but tried to minimise them by presenting it in

the form of a risk-benefit analysis.

“If the benefits outweigh the risks then it is worth taking the risks. Side effects are nothing compared to the lifelong problem a woman faces due to infertility.”

They also attempted to individualise the side effects:

“Drugs are used to stimulate the process, but side effects vary from person to person. For example, if I have aspirin it may not react, but for some other person it might.”

It was only after probing that they mentioned risks such as: ovarian hyperstimulation syndrome, a life-threatening complication of the drugs used to stimulate production of eggs; multiple pregnancy as one of the outcomes of a stimulated IUI cycle or IVF (they did not feel this to be an adverse effect); obesity, allergic drug reaction, miscarriage, edema, ectopic pregnancy, and ovarian cancer, and risks such as perforation associated with the process of egg retrieval.

The providers attempt to place the burden of risks and complications of the procedures on the women, who “willingly” undergo the procedure to have a child. In an attempt to “justify” or “defend” potentially risky techniques, these side effects are portrayed as minor, negligible in comparison to the necessity and “desirability” of having a child.

Women’s Perceptions/Experiences

Three women categorically stated that they “did not experience any discomfort” from the procedures, or “there were no side effects of the drugs”. Thirteen women reported facing some side effects but were not sure whether they were related to the treatment. Ten women mentioned what were clearly side effects of the drugs. Primary among these were weight gain, fatigue, increased micturation, mood swings, giddiness, skin rashes, fevers, hot flashes and a feeling of bloatedness. Two also described the pain of the laparoscopy... “*u durbin laga ke* (the way the laparoscope lens was inserted). That was painful...”

However, it seemed that most women had accepted the pain and side effects as something minor and integral to the “treatment”. This reasoning of a risk-benefit analysis had been offered to them by their providers, and asserted the fact that all this had to be endured in order to get the desired child.

Informed Consent

Providers’ Perspective

Only nine among the 23 providers mentioned the use

of an informed consent form and only two agreed to share their forms with the interviewers. Three said that their informed consent forms were photocopies of the ICMR guidelines and four said that they had different informed consent forms for different procedures. One provider said, “Both the partners are asked to sign the informed consent forms at the time of registration for the IVF cycle.” Another said, “The informed consent forms are both in English and the local language.” Two said, “All side effects are mentioned clearly” and “We explain everything to them and sometimes they sign the form without even reading it.” Three providers stated that informed consent forms are basically disclaimers to ensure that the clinic will not be held responsible in case of any complications or problems.

Women’s Perspective

The information obtained from the women participants on the issue of informed consent was also very sketchy. Seventeen women spoke about the informed consent forms. Six said that they had never signed any informed consent form — or any written material for that matter — while going for IUI. Six said that they had signed informed consent forms or some other kind of written material while going for IVF. One woman said that she did not sign any informed consent form even for IVF. Another said that though she did not sign any informed consent form during IUI, she signed a consent form while registering for IVF. In sum, only seven of the 25 women interviewed reported signing an informed consent form which they read – or which was read out to them.

Regarding the content of the informed consent forms, four said that they did not have any idea as their husbands signed it on their behalf. Three were of the view that informed consent forms are mere disclaimers protecting doctors in case of complications that may result from these procedures. Only one woman, said, “Yes, we signed an informed consent form. I read the form—it had details of the side effects and the success rates.” Another woman said, “We signed the informed consent form which was in English. As we don’t understand English, the doctor narrated the contents to us in Telugu. The doctor told us that there may be some side effects and also that the success rate was low.”

It appears that informed consent was rarely obtained from women before undergoing procedures of ARTs. Even when these forms were signed, it was usually by the husbands, and very rarely by both partners. All the necessary information needed to formulate a truly informed choice, was usually not disclosed. The language in which the informed consent forms were drafted also made it difficult for everyone to understand

them.

Success of These Techniques

As Quoted by Providers

Often, the implantation rate or the chemical pregnancy rate was quoted as the success rate, rather than the live births rate or the “take home baby” rate – the number of pregnancies that result in the birth of a child that survives. Providers seem to be manipulating these various definitions to their own advantage, using them to promote ARTs in general and their provision of them in particular. The argument for quoting the implantation rate rather than the live births rate was that women were referred to them for infertility treatment and went back to their gynaecologists once they conceived. Hence, it was not possible to keep track of the take home baby rate.

It is only on probing that the take home baby rate was quoted. Two of the 23 providers directly mentioned the take home baby rate as the success rate.

Ten providers cited the implantation rate of IUI in their clinics, and these ranged from 15 percent to 50 per cent. On further probing however, some of them also offered the take home baby rate. Six said it was “almost” the same as the implantation rate. One said the take home baby rate was between 8 per cent and 12 per cent. One did not provide the take home baby rate at all. Similar responses and widely varying ranges of success rates were given during the discussions on the success rates of IVF.

There was a significant difference between the implantation rates and take home baby rates quoted by providers. One provider suggested that this was because many women miscarry due to their own carelessness: “Women return to their respective gynaecologists for delivery” and “don’t take proper care of themselves once the implantation process is over”.

It is difficult to have a clear idea of the success rates of these technologies in the Indian context, given the absence of a central registry for ART clinics and the use of standardised definitions for success rates.

As Experienced by Women

The most striking feature was the number of ART cycles that the women were willing to endure. Fourteen of the 25 women interviewed went through IUI. Five women conceived, one in the first cycle, one in the second cycle, two in their third cycle and one in the fifth cycle. Three women reported having undergone two to three

cycles, four women had undergone four to six cycles. One woman had gone through eight cycles and not one of these had resulted even in an implantation of an embryo.

Four of the remaining 11 women had undergone IVF. Three had become pregnant.

Three of the 25 women went through all three procedures - IUI, IVF, and IVF-ICSI. Only one of these three women became pregnant, in the second IVF-ICSI cycle. Before she became pregnant, she underwent five IUIs, one IVF and one IVF-ICSI. One woman underwent three IUIs followed by one IVF. One woman had two IVFs followed by five IUIs, all of which failed. One reason they may have persisted is their doctors’ individualising the success rate of the techniques:

“What is there even if the doctor says that the success rate is this much? Ultimately whether it will be a success or not depends on individual bodily constitution. Some people conceive after one IUI and some don’t even after several cycles of IUIs and IVFs.”

It is frightening that so many women, even in our small study sample, repeatedly put themselves through uncomfortable procedures in order to get pregnant and bear a child. This is how couples enter the slippery slope of reproductive technology. It is almost impossible for them to first decide when enough will be enough.⁹ Added to the guilt of not being able to conceive is the guilt of “not having tried hard enough.”

Information Regarding Egg Retrieval and Implantation

Among the providers interviewed, six commented on egg retrieval, stating that the number of eggs retrieved depends on individual women. The range varied from five to 16 eggs. In one case, a provider claimed to have retrieved 35 eggs. Regarding the maximum number of embryos implanted in one IVF cycle, eight providers responded saying that it varies between two to five, with three being the most common.

Of the eight women who underwent either IVF or IVF-ICSI procedure, three did not have any information regarding number of eggs retrieved, eggs implanted and what happened to the rest of the eggs. Their bewilderment on the lack of information was aptly reflected when a woman said, “We don’t have any idea of how many eggs were retrieved or how many were implanted. Only the doctor knows that.”

Retrieving large number of eggs (as in the case of retrieval of 35 eggs), requires hyper stimulating the ovaries through intake of hormonal drugs, which often entails serious medical complications for women.

Moreover, the procedure in itself is highly invasive, and may result in serious damage/harm to the woman undergoing it. There was somehow also a feeling among the women that it was their own responsibility to ask and know about such information and not the doctor's duty to provide it to them voluntarily. Thus, in most cases they did not blame their doctor for not giving the information but felt that it was their lack of experience or knowledge, which made them refrain from asking questions. However, this practice of providing selective information without considering the consequences of this for women, calls into question the ethics of medical practices.

Conclusion

A woman's role as a mother is both elevated and venerated to the exclusion of other roles that she may play in society. It is in this social context that the pressure on women to bear a child is immense, and which has thereby enabled the rapid growth of the ART industry here. The industry has also used the existence of this social pressure to justify the existence of ARTs and to portray them as benefiting women. They have, in fact, reinforced this societal belief in the linear progression of marriage, motherhood and womanhood, to the point of excluding alternate forms of parenthood or voluntary childlessness.

At the level of level of medical implications of ARTs, the study highlighted that there are various health risks involved, both as side effects of drugs taken, and complications of the procedures themselves. Some of these are potentially very hazardous, and therefore need to be disclosed in detail to the women wanting to opt for ARTs. The failure to do so, bring us to the ethical dilemmas raised by ARTs.

As stated earlier, good medical practice should entail the complete disclosure of information pertaining to risks and complications, its efficacy, and existing alternatives to the treatment. However, our small study sample depicts discrepancies and gaps on this front. Information was often piecemeal and inadequate. The side effects are described as minimal, negligible and affecting only a few. Success rates are inflated. Most women seem to have received an unrealistically optimistic picture of ARTs. This comes in the way of a truly informed choice needed in undertaking any treatment.

Another ethical dilemma posed by ARTs is the increasing commodification of the female body, with reproductive body parts like sperm, ova and uteri being bought, sold and rented in the market for profit. This process will surely worsen the exploitation of women who already face oppressions of various kinds, social and economic.

These are some issues related to ARTs that deserve a critical review before these techniques are endorsed as liberating women by endowing them with choice. This deserves special attention in the face of an absence of an effective regulatory system.¹⁰

Endnotes

¹ Born through *in vitro* fertilisation in Oldham, Lancashire, in 1978, under the 'care' of Dr Robert G Edwards and Dr. Patrick Steptoe.

² This led to him being extensively criticized in the medical community. Following this, Dr. Mukherjee committed suicide in 1981.

³ National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, ICMR ,2005

⁴ ICMR, 2005, op.cit.

⁵ Quoted in *ARTs and Women: Assistance in Reproduction or Subjugation?*, Sama, 2007, pp 35

⁶ Sama-Resource group for Women and Health is a Delhi-based organization, dealing primarily with issues of gender and health. Our four primary activities involve, training and capacity building; policy advocacy; material production and dissemination; and action research. The Sama team involved in the study comprised of N. B. Sarojini, Manjeer Mukherjee, Preeti Nayak, Riddhi Bhandari, Suchita Chakravarty, Deepa Venkatachalam, Anuj Kapilashrami, Roshni Subhash, Beenu Rawat and Saswati Bhattacharya. We would like to extend special thanks to Sandhya Srinivasan for overseeing the process of editing, along with giving helpful inputs.

⁷ Study by Sama, Delhi, was carried out in the three cities of Delhi, Mumbai and Hyderabad. The report has been published as *ARTs and Women: Assistance in Reproduction or Subjugation?*, 2006.

⁸ Maria Mies, "New Reproductive Technologies: Sexist and Racist Implications," *Quilt*, 09-01-1994, pp 41+ (Asian Women's Human Rights Council, 1994)

⁹ < http://www.christinemorton.com/CHM/S0000_week04.htm >

¹⁰ The regulatory guidelines for ARTs in India are ICMR, *National Guidelines for Accreditation, Supervision and Regulation of ART clinics in India*. 2005. However, they have been criticized as reflecting social biases and containing many loopholes. They are also not enforceable. For a critique of the ICMR guidelines, refer to "Ethical issues in ARTs and the status of regulation," chapter 5, in the Sama study report, *ARTs and Women: Assistance in Reproduction or Subjugation?* Sama, 2006.

Will India Learn Ever from Thailand?¹

Thailand considered more "beholden" to the US than India has taken the courageous step to introduce Compulsory Licenses (CLs) for 3 drugs that were unaffordable for the majority of its people. India can learn from Thailand how to use the flexibilities in the TRIPS/Doha Agreement and our own amended Patents Act 1970.

Issue No. 5: The Government Use of Patents will save the government some funds but what are the benefits to the people?

The main objective of announcing and implementing the Government Use of patent is to *increase the access to essential medicines among the Thai people*. The government does not save any budget and in some cases has to spend more. For those ARVs which have limited coverage, like Efavirenz and Lopinavir+Ritonavir, many more people will have access to the drugs with the same budget level. In the case of Clopidogrel, the patients under the National Public Health Insurance Plan had no or very little access before, and the government had to pay an additional amount to allow access to the lower priced generic version of Clopidogrel. It should be reiterated that drugs derived from the implementation of the three Government Use of patent will be distributed only to those patients under any of the three public health insurance plans paid by the government.

The drugs can not be sold to the private sector or to those who are willing to pay out of pocket for their drugs.

The benefits to the Thai people from the Government Use of patent on each drug are:

1. The Case of Efavirenz Patented by Merck Sharp and Dohme (Thailand) Limited

Efavirenz is an effective first line ARVs. It is less toxic than Nevirapine which is used in the locally produced Nevirapine based triple ARV formula, GPO-VIR®.

Around 20 per cent of patients using GPO-VIR® will develop adverse drug reactions, from mild to severe, which can be life threatening. Patients in developed countries use Efavirenz based triple ARVs as their first line treatment, including developing countries that purchase drugs through external aid budgets. In Thailand, due to the high price of Efavirenz, all new cases of AIDs patients will have to be put on the more toxic Nevirapine based triple ARVs as their first line treatment. Around 20 per cent of them develop adverse reactions to the GPO-VIR®. Only when they develop severe adverse drug reactions will they be switched to the Efavirenz based one, which is more than twice the price of GPO-VIR®.

With the Government Use of Patent, the Efavirenz price dropped from 1,400 Baht per month to 650 Baht per month. This will allow 20,000 more new patients to be put on to this Efavirenz based triple ARVs and reduce the risks from the toxicity of the Nevirapine based triple ARVs. If we allow competition to continue under the Government Use of Patent, it is expected that the price may go down further. If the price goes down to 20 per cent of the original price, then we will be able to support up to 100,000 patients with the same budget. This will allow all new patients to be treated with Efavirenz based triple ARVs in the next 5 years. There will be no need to subject the new AIDs patients with the more toxic Nevirapine based ARVs anymore.

2. The Case of Lopinavir+Ritonavir Patented by the Abbott Laboratories Limited

The Department of Disease Control has done a study on drug resistance among patients taking the first line ARVs. They found that around 10 per cent will develop drug resistance and will require second line ARVs, in the first few years. This depends mainly on the compliance of the patient and the virus itself. There are now around 500,000 people living with HIV/AIDs in Thailand. In the near future, at least 50,000 of them will require second line ARVs. One of the good second line drugs is the combination between Lopinavir and Ritonavir, patented by Abbott Laboratories Limited, under the trade name of Kaletra®. The monthly price for the patented product is around 6,000 Baht in 2007. This means 72,000 Baht per patient per year. The budget required for 50,000 patients will amount to 3,600 million Baht. This is more than 100 per cent of the budget for ARVs in 2007. There is still the need to pay for the more than 100,000 patients on first line ARVs. If they do not receive

¹Source: *Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand*. Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent by the Ministry of Public Health and the National Health Security Office, Thailand, February 2007. Also at <<http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf>>

second line ARVs, they will soon develop opportunistic infections and die. These are deaths occurring in the midst of the availability of the appropriate treatment.

The high price of the second line ARVs are the major factors that hinders the attempt to save their lives. At the moment, we are able to support less than 2,000 cases of drug resistant patients. With the Government Use of Patent, we expect the drug price to go down at least to around 20 per cent of the current price, which will allow us to save an additional 8,000 lives. With more competition and increased budget, we will be able to save more lives in the near future.

3. The Case of Clopidogrel Patented by Sanofi-Aventis Limited

This is an anti-platelet drug which is at least as effective as or more effective than Aspirin in preventing coronary obstruction. It is commonly used in patients with coronary heart diseases which are estimated to be around 300,000 patients in Thailand. It is almost the only drug that can be used in the case of applying coronary artery stent. However, due to the very high price of 73 Baht per day, only around 30,000 patients can afford it, based mainly on out of pocket payment.

So, the rest of the poor people who cannot afford to pay have to live with only Acetyl Salicylic Acid. The Permanent Secretary announcement of the Government Use of its patent will reduce the price at least 10 times to less than 7 Baht and allow patients under the universal health insurance scheme to also have access to the drugs. In this case the government and especially the contracted hospitals have to pay additional budget to support access to these generics. However, the lower price generics make it affordable by the government.

From the three examples above, it is clear that the Thai government's goal in implementing the Government Use of patent is to increase the access to the patented essential drugs, rather than to save budget. In the case of Clopidogrel, it is clear that more funds will be needed, but is within affordable limit.

Issue No. 6: What will be the implications on the Thai export and economy and multinational industries be in Thailand?

The first thing to consider in addressing this question is that Thailand is implementing the

Government Use of patent in compliance with national and international legal frameworks, based on solid evidences of the need to allow the Thai citizens to have more access to patented essential drugs. Furthermore, we are happy to negotiate and discuss with all the patent holders in a constructive manner for the benefits of all stakeholders. Thus there should not be inappropriate reactions and trade retaliation from our trade partners.

The Ministry of Public Health is fully aware that at least two-thirds of our economy depends on exporting of our goods and services. Furthermore, 15 to 18 per cent of our exports go to the USA, the country of origin of two of the patent holders that we have implemented the Government Use. If the US government applies retaliation measures on our exports which results in 10 per cent reduction of exports to the US market, it will mean a one to 1.2 per cent loss of economy and several hundred thousands job losses. So this is a very sensitive issue. Unless there is very important need for the people supported by solid evidences, we will not make these decisions.

So the decision on the Government Use of Patent for the three drugs has been made very carefully based on solid legal and social grounds. It should be noted that a few daily newspapers in Thailand had reported in mid February that the Trade Counselor of the US Embassy in Thailand has informed the senior official of the Thai Ministry of Commerce that the US will not use this case in their consideration of the status of Thailand in their list of countries trade relation. This is good news and it provides evidence of the US fair trade policy. However, there has been no official confirmation on both sides, so far.

Nevertheless, if there is unfair trade retaliation against Thai products/services which is not in compliance with the WTO trade rules, we will have the right to bring the case to the Dispute Settlement Body of the WTO.

Furthermore, it should be reiterated that the Government Use of Patent does not touch on the out of pocket payment market, the current market of the patented drugs. The Government Use only opens new market for those who never have access to these drugs before. The patent holders have the full right to reduce their price to compete with the generics in this new market.

So after the Government Use of Patent, there will be two drug markets in Thailand. One for those well off

(contd. on page 32)

(contd. from page 31)

people and the two million foreign patients who pay out of pocket for the high price monopolized patented drugs. This market covers around 15-20 per cent of the population. The other is for those who are paid by the government for the lower priced competitive drugs. This is the majority of the Thai people who use their rights under the universal health insurance schemes.

In addition, the size of the Thai drug market is less than 0.5 per cent of the global drug market. It is even less for the market of patented drugs. So there should not be significant effect on the market and return of the research based drug companies.

On the contrary, the Government Use will allow the local pharmaceutical manufacturers, especially the Government Pharmaceutical Organization, to develop their capacities and products. In case that the discussion and negotiation leads to the agreement on voluntary licensing, there will also be technology transfer to further strengthen the local manufacturing capacity in Thailand.

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