THE MASHELKAR REPORT: A TRAGEDY OF THE COMMONS

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The end of the year 2005 proved to be disastrous for several Asian countries including India due to the huge impact of the Tsunami. The Mashelkar report, which was released at the end of 2006, makes the Tsunami of the year. When champions of social engineering like Dr. Madhava Menon sign a report that lacks in proper legal analysis and fails to balance legal with social issues, it is time for the red flag to go up. It is what we call as the *Tragedy of the Commons.*

I would like to criticize the report for two main reasons: First, the report lacks appropriate legal analysis or scholarship the superimposing social issues that it sets out to balance with the legal issues. Thus, my criticism is not necessarily because of the report's conclusions. Instead, this paper concludes that the conclusions of the report are negligible because of its lack of proper analysis. The report's conclusion seems to be pre-drawn and merely pasted onto the report. In short, the report is fitting from a law student, a wanna-be-lawyer, but, is a Christmas surprise when released from scholars of Mashelkar and Menon's status.

Question taken by the report: The Report analyzes two narrow question under the Patent Act, 2005.

The first question addressed by the report is, whether granting of patent protection can be limited to a new chemical or medical entity that embodies an inventive step.

The second question is whether microorganisms should be 'granted patent protection.

Considering that the Patent Act, 1970 was amended in order to fulfill India's TRIPS obligations[2], the larger question is whether excluding one or more of the above would violate the terms of the TRIPS agreement.

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2. These refer to the obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights which was signed in 1993 as part of the Agreement Establishing the World Trade Organization (WTO).

The first question implicates issues of patentability and the second implicates issues of patent eligibility. The term patent eligibility (a term of art, which is unfortunately never used in the report), refers to the question of whether the subject matter (area of science) is patent eligible. That is, assuming the invention in question is in the area of bio-genetics. The question would be whether all bio-genetics is excluded from patent protection.

This question is different from the issue of is patentable - the question of patentability is determined by whether a particular invention can be patentable. A particular invention would not be patentable, even if it falls within a patent eligible subject matter, if it does not fulfill tests of utility, novelty and nonobviousness (inventive step).

In essence, the first question is framed to state that while new chemical and medical entities are patent eligible subject matters, the question is whether India can limit the grant of patent for substances embodying such patents with a view to balance social with legal issues (or trade with welfare issues).

The second question is meant to analyze whether microorganisms can be fully excluded from patent eligible subject matters.

Discussions on New Chemical Entity

The report highlights that patent protection cannot be limited to "new chemical entities.:" Basically, the report states that ALL chemical entities are entitled to patent protection. The breadth of the statement signifies, perhaps, a flawed understanding of patent law.

Any invention has to fulfill three important criteria before it becomes eligible for patent protection. These criterions are utility, novelty and nonobviousness (inventive step). An invention that does not fulfill even one of these criteria would be refused patents even in the United States.

Article 27(1) of TRIPS requires the following :

> ... patents shall be available for any inventions, whether products or processes in all fields of technology, provided that are new, involve an inventive step and are capable of industrial application."

Thus, patent protection for all inventions (leave alone new chemical or medical entities) requires the invention to be new, useful and embody an inventive step. Novelty and nonobviousness along with utility are threshold requirements for patenting.

1. The report concludes that chemical entities that are not NEW, can still be eligible for patent protection. "Granting patents only to New Chemical

and Medical entities and thereby excluding other categories of pharmaceutical inventions is likely to contravene the mandate under Article 27 to grant patents to all inventions." Unfortunately, in order to qualify as invention, among other things, the invention has to be *new.*

Generally, what is "new" is defined by national statutes. There is nothing in TRIPS that necessitates a definition of novelty. For instance, the United States defines what is new under 35 USC $ 102. The definition excludes matters that the United States Congress (and not the TRIPS agreement or the WTO) believes is not new. For instance, &102 treats matters that are publicly used in other countries but unknown in the US as being new. That is why Indian turmeric and neem were not barred as lacking novelty. Europe also does not allow patent protection for matters that are not novel. Novelty is a threshold requirement for protection in the United Kingdom, Germany and in all other western European Countries. There is no compulsion or requirement under the TRIPS to define novelty one way or the other.

Considering the above, the report's statement that all chemical entities, new or otherwise are entitled to patent protection is clearly and dangerously erroneous.

Notably, if a chemical is not new, (that is, the product is a known product) it can also not pass the test of inventive step. Thus, a product that fails the novelty test will also fail the inventive test. In order to pass that of inventiveness, the invention has to embody something inventive when compared with the existing state of knowledge. Thus, for known products, the simple question is whether a new use of a known product is patentable, which is what, I suspect, the Report probably set out to find in a clumsy manner.

2. As for the question of whether a new use of a known product is patentable, the question boils down to what India believes qualifies as an *invention.* If India believes that the same known substance for which a new use is discovered should be eligible for another patent, then it should widen the definition. TRIPS does not concern itself with the narrow issue of defining the scope of an invention. As a mark of the flexibility, members of World Trade Organization approach the question differently. For instance, the United States does not allow patenting of new uses of known substances. Hence, protection is in fact limited in the United States to chemicals that are new, embodies an inventive step and has commercial utility. It is almost funny to note that report quotes several

countries without actually stating this important factum of the United States.

Similarly, the European Union also limits protection for new chemical entities. Under the European Paten Office Guidelines ("EPO Guidelines"), a allowed provided a *new use* of the product is disclosed. In Europe such patents are titled " use innovations" and can be protected using "purpose-limited-product claims." These claims limit the scope of patent protection to the particular purpose or use of the product. Thus, Europe actually goes one step further than the United States to provide patent protection for identical products, subject to claiming a new use (and not on inventive steps). The European practice arose from a 1979 application for pyrrolidine derivatives. The patent application contained active therapeutic substances to reduce cerebral insufficiency. The derivatives destroyed novelty even though the pharmaceutical use of the derivatives was unknown. ([1984] E.P.O.R.591). Generally, the purpose- limited-product claims are used only when the application materials is already known and patented but the application claims a new use.

In 1984, the European Patent Board in EISAI (1984]E.P.O.R.241) reiterated that claims directed to the use of a known substance or composition of the manufacture of a pharmaceutical preparation for a specified new and inventive therapeutic application will be eligible for European patent protection. Thus in Europe, the first new use (usually medical) of a known product (protected by a product patent) is patentable by the use of a purpose-limited-product claim. The second and further use of the same substance or composition for the manufacture of the specific inventive application (usually therapeutic). Known as "Swiss claims," the claim format protects the *new* use of the known compound or composition.

The bottom line is that the patent provision of TRIPS does not dictate how a country has to define invention and whether the definition of invention should vest patent protection over known products with new use or improvements.

The Report unfortunately cites Article 39.3 of the TRIPS agreement in support of its conclusion that patent protection need not be limited to new chemical entities. The most interesting part of Article 39 is that it does not deal with patent protection. It deals with undisclosed information (generally known as trade secretes). The article itself states that,

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products

> which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

It is mere condition of marketing. The articles limited requirement is directed at the agency approving the marketing of pharmaceuticals chemicals. The article mandates the agency to ensure that is designated by the applicant as a trade secret should be disclosed, either to the public or as part of the marketing label of the invention. Even this disclosure can be done away with for reasons of public interest.

It is most depressing to note that the members ignored the public interest exception that is a part of that section itself.

In essence, assuming a known product is being marketed on account of a new use. The marketing has to be approved by an agency that is equivalent of the FDA (Food and Drug Administration) in the United States. In India, such an agency would fall within the realm of the Narcotic Drugs and Psychtropic Substances Act, 1985. Assuming that Researcher Rani makes an application to market a known product but embodying a new use. Rani wants to ensure that her test data remains a secret. It is a TRIPS imposed duty of the authority to ensure that her test data is treated as a secret. However, if the authority determines that the test data is treated is required to protect public interest, then the authority can basically state that the information is not eligible for being treated as undisclosed information.

If TRIPS wanted the information to be protected by patents, it would clearly be within the patent provision of TRIPS. Surely, the members of the Msahelkar Committee did not think that the drafters of the TRIPS agreement meant to treat undisclosed information (that may or may not be eligible for patent protection) as patentable but decided to include it as part of the section on Undisclosed Information.

Discussions on New Medical Entity

The report does not clarify what is a new medical entity. Is it the process of medical treatment or is it a product of medical treatment or is it a known compound that exhibits pharmaceutical properties. All western countries treat each of these questions separately for the purposes of patent protection.

Method of Medical Treatment

Should a new method say, of cutting the body open for a surgery, or doing a cataract surgery be entitled to a separate patent. For example, assuming Dr. Sita discovers that for C-section deliveries of babies, making an incision curved at a particular angle allows quicker delivery while at the same time facilitating a faster recovery. Allowing it to be patented would necessitate that anytime any doctor uses that curved incision to deliver a baby, Dr. Sita would make royalties over it for the next twenty years. It also means that patients who cannot afford that royalty would not benefit from deliveries that necessitate a curved incision. The question is whether such methods of medical treatment ought to be patented.

Several countries exclude methods of medical treatment from patenting and on grounds of public interest. The United States allows such patents but eliminates all remedies for infringement against medical practitioners or a related health care entity for the use of the patented technique under § 287(c) of Title 35. In essence, while the method is patentable, it is also freely available for others to copy (for public interest purposes).

New Product or composition used for medical treatment: A new product that involves an inventive step for medical treatment has to go through the same steps for patentability as any other invention. Thus, a new product for medical treatment should be new, nonobvious (inventive step) and have commercial utility in order to be patentable. Patent protection for such products can be exempted under the terms of the Doha Declaration read with the relevant provisions of the TRIPS agreement.

Know Product used for Medical Treatment : If a product is known, naturally it simply cannot pass the test of inventive step. Hence, it boils down to the question to vesting patent protection to a known product with a new use, which in turn goes back to the issue of whether it would fall within the definition of the term invention. Again, the United States does not allow patenting of new uses of known medical products. Either the process of making the product has to be novel or the product has to embody something new before it can pass the test of patenting.

Notwithstanding all of the above, as a matter of general interest, it might be interesting for India to know that one of the biggest debates currently raging in the United States is against patent eligibility. Even big businesses corporations (the IBM and pharmaceutical giant *Eli Lilly* being the newest members) have opined that the expanding scope of patent protection has actually led to a decrease in innovation.

Public Interest Exceptions for Known Chemical and Medical Entities that Embodies a New Utility

The Meshelkar report cites Article 7 and 8 of TRIPS read with the Dohas Declaration to determine that patent protection cannot be limited to new and nonobvious chemical or medical entities.

In reality, TRIPS does not concern itself with the narrow question what would amount to an invention as long as novelty, utility and nonbviousness are the three broad criterion under which the inventiveness is determined. That is, TRIPS does not state how the term invention has to be defined. India is well within its rights, under the TRIPS agreement, to define inventions to limit protection to new chemical and medical products embodying an inventive step. There is nothing in the patent provision of the TRIPS that forces India, or any member for that matter, to define inventions as embodying known products with just new uses.

Finally, as a lip service to the social issues, the Mashelkar report distinguishes "ever greening" from protecting incremental innovation. To that extent, the objective of the report is very respectable. But the report moves on to state that "restricting patentability just to new chemical and medical entities" could be in violation of TRIPS. In effect, the report basically suggests that all chemical entities and medical entities should be patented - even those that are not new and already in the public domain. Yes, let us go ahead and take from the public domain and move it to the private domain. Even the champions of patenting like the United States would find that statement unacceptable. Surely, though, this is the best way to get Big Pharma to scout for 'social engineers' from the National University of Juridical Sciences. It is a classic case of Robin Hood on the reverse.

Patent Eligibility of Microorganisms

The last question the report examines relates to the question of whether microorganisms are patentable. The roots of the issue can be traced back to Article 27.3 of the TRIPS agreement.

Article 27 (1) of TRIPS states that ..... "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." Further, Article 27(3) (b) highlights that members may exclude from patentability ... plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

TRIPS, therefore mandates that microorganism should be protected. But, when read with Article 27(1), TRIPS requires only microbiological organisms that qualify as an invention to be protected. In order to qualify as an invention, it is not enough that the microorganism has a utility, it should also be *new* (genetically engineered/not known before) and embodies an inventive step.

The report concludes that new microorganisms isolated for the first time from natural surroundings can only be patented if they differ in characters and find new or improved uses. Even countries like the United States (known for overreaching when it comes to protection of genes and microorganisms) do not allow patenting of all microorganisms. The Manual for Patent Examination Procedure has outlined criterion that has be cleared before microorganisms can protected.

Even the case that established worldwide protection for microorganism being *Diamond v. Chakrabarthy,*(447 U.S. 303(1980)), specifically outlines that anything "made under the sun by the hands of man" is patentable. Thus, even microorganisms have to be made *by the hands of man in order* in order to be patentable. It is not enough if is simply newly discovered. The United States Supreme Court established the proposition in the case of *Funk Brothers,*(333 U.S.127(1948)) where protection was denied to a bacterium that furthered the breaking down of nitrogen in leguminous plants on the grounds that the bacterium was merely discovered as against invented.

The answer to the question of whether microorganisms should be patent eligible is easy to answer in the context of TRIPS. The larger question of patentability of microorganisms deserves an in-depth and closer study. For instance, is a newly genetically engineered microorganism protectable because it is potentially useful for further research or it is protectable because in some tests the new organism seems to exhibit properties that shows its potential use against certain diseases or is it protectable because research has conclusively proved that the microorganism is a cure against a specific disease. The answer to this question is purely a matter sovereign determination. Basically, it is upto India and the government to determine when the utility requirement would be considered fulfilled.

That is, assuming that Researcher Raman derives a genetically engineered microorganism MX. Now, nobody, including Raman, knows what MX is useful for. But everyone knows that MX can be researched upon further to determine its real use. The question is whether we grant protection to Raman just because MX can be used as a tool for research. Even developed nations like the United States require that a proper use has to be determined before the microorganism

becomes patentable. For instance, the Supreme Court of the United States in *Brenner v. Mansom* (383 U.S. 519) in 1966, held that a patent is not a hunting license in the context of a biotechnological invention whose biggest use was only as a tool for further research. The court highlighted that a patent is not a reward "for the search but a compensation for successful completion." Moreover, in the United States, the Patent and Trademarks office also acts as gatekeepers by requiring substantial and specific utility of the microorganisms to fulfill the utility requirement. Furthermore, the patent office also embodies a heightened standard of written description and enablement for biotechnology patent applications. Basically, it requires applications for biotechnology inventions to specify how to make and how to use the invention clearly in order for the invention to be considered completed.

The Mashelkar report should have deliberated on what amounts to successful completion of research to determine the threshold requirements for microbiological innovations. As such, the conclusion of the Mashelkar report gives the impression that all microorganisms -even those that are merely research tools-are eligible for patent protection.

The danger of allowing patent protection for inventions on microorganisms whose use is merely as a research tool is that it would block competition and further research. In the example above, for instance, if a patent is awarded to Raman for MX and if he assigns it to Company A, only Company A can research on the microorganism MX. Other companies like Company B, for instance,

that wants to research on MX would be required to pay a royalty to Company A to even do research on that microorganism. Consequently, the following happens:

1. The ultimate cost of a drug when one is fully invented using MX as a research tool, will involve cost of the royalty to get the permission to work on MX and the cost of the research of Company B.

2. The more such tools of research are pantented, soon the industry finds itself having to license several research tools which in itself becomes cost prohibitive. Ultimately, that cost if borne by the consumer.

3. Naturally, as more research tools are protected by patents, the incentive to actually conclude a research is gone. If Raman can become a millionaire by just inventing a microorganism without telling the world what it is useful for, Ramsn would not wait to determine the ultimate use. Companies also start making money by just creating research tools rather than research itself.

4. Research becomes procedurally cumbersome because it involves a lot of paper work and litigation.

5. It would increase the burden of the courts and would lead to more unnecessary cases on whether a research tool was used without proper licensing. Basically, it would elevate the importance of licensing lawyers.

6. Naturally, all of these slows and stifles research.

In a paper titled "The Tragedy of the Anti-commons: Property in the Transition from Marx to Markets" Professors Michael Heller and Rebecca Eisenberg outline how competing patent rights on research tool prevent useful and affordable products from reaching the marketplace.

It is important for a country like India to determine at what stage and when a genetically modified microorganism becomes patentable. That is what was perhaps expected from the report-a careful consideration of the various ramifications and to ultimately suggest the boundaries for patent protection for patent protection for micro-organism. The report unfortunately concludes before for patent protection for micro-organism. The report unfortunately concludes before grasping the question.

The other interesting feature that report does not highlight is that the fact the US Patent and Trademarks Office has been under huge criticism for allowing biotechnology patents on research tools. Currently, a part of the academic and business community of the United States strongly opines that both business methods patents (which Europe has not yet adopted) and biotechnology patents have stifled rather than furthered research by vesting patents on research tools. In fact, the Federal Circuit on Feb 8, 2007 heard oral arguments on the issues relating to patentability of physical signals *(In Re Nuijten)*. Another important case on the same issue *In Re Fisher & Lalgudi* 421F. 3d 1365 (2005) relates to a patent application for an expressed sequence tags (ESTs which is a gene fragment) of maize which the Patent office dismissed as unpatentable on account of patent community that the case would, on appeal, result in the Supreme Court setting adequate boundaries of patent eligibility

Conclusion

In short, the Mashelkar report is an insult to the Incredible India that the Government has promoted in every airport across the country. Perhaps it is time for the Indian Government to establish a committee involving experts a) in patent law, b) with knowledge of social realities and c) members who can be potentially impartial to external pressures. After all, when TRIPS itself allows flexibilities and when even nations like the United States exploits the TRIPS,

India's stregth would lie in fully utilizing them. Understanding this new area of law and working it to the benefit of Indian national objectives is the key to future success. *Benefit* to the nation accrues when innovation is promoted while balancing trade obligations. After all, if notwithstanding, the resulting loss of productivity would eat into the frruits of globalization.