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THE ORANGE PILL, NOW IN 3D: REWRITING PATENT HISTORY?

"Pharmaceutical companies that have invested in the development of medicines should achieve a return on their investments. But this does not mean the abuse of these exclusive rights by excessive prices and seeking patents over minor changes to extend monopoly prices. This goes against the spirit of the patent system and is not justified given the vital investments made by the public sector over decades that make the discovery of these medicines possible.

…

"Public institutions around the world have continuously played a critical role in the research that leads to vital new medicines reaching the market. Without access medical research becomes a luxury good. Most of my colleagues would be very uncomfortable if we felt that this would be the result of our decades of effort."

—Dr. Brian Druker, one of the scientists who developed *imatinib*
The Mint, 15 August 2007

On its release, *It* was a runaway blockbuster raking in millions of dollars in *Its* first year. Almost a decade after *Its* release, *It* now rakes in billions of dollars annually. Having bagged several awards the world over, *It* was expected to make a clean sweep in India too. But, then *Its* award-run took a turn. The primary reason: The 3d experience in India. To complete *Its* golden run of picking up awards, *It* had to pass the hurdle set up by Indian Parliament: how would *It* appear when viewed in 3d? Having failed to cross over the 3d hurdle, *Its* producers have now brought *Its* case to the Indian Judiciary in a plea to lower the hurdle.

It, which in the words of *Its* producers had "re-written medical history", has now been brought by *Its* producers to the dockets of the Supreme Court of India in what may be *Its* attempt to rewrite history yet again. This time, the history *It* seeks to rewrite is that of the patent law of India.

The "*It*", under reference, is the "Orange Pill", the expression used by Novartis AG's Chairperson Vasella and his co-author in *Magic Cancer Bullet: How a Tiny Orange Pill is Rewriting Medical History* to describe the beta-crystalline form of *imatinib mesylate* (*Gleevec*), a medicine used to treat chronic myeloid leukemia. The awards are the patents that have been granted to the Orange Pill in various jurisdictions. And the case before the Supreme Court of India is the litigation between Novartis AG, on the one hand, and the Government of India, cancer patients and Indian generic companies, on the other.

What is the background of this case? Why is this case relevant? To find out more about it, we invite you to read on.

Contents **Page No.**

What will be decided?

Presently, India is one of the world's largest producers of low cost and high quality generic medicines. Over 80 percent of antiretrovirals to treat HIV purchased by developing countries are from Indian generic companies.

One of the primary reasons for India's ability to be a source of generic medicines for the whole world is that, between 1972 and 2005, it did not provide product patent protection for medicines.

If the Indian patent office starts to routinely grant product patents on medicines, as is the situation in most other countries, India will no longer be able to supply these medicines.

From 2005 onwards, due to a change in its patent law, India has started granting product patents to medicines. However, there is a public health safeguard in its patent law, section 3(d). Section 3(d) seeks to prevent patenting of new forms of known substances unless they exhibit enhanced efficacy. Were it not for section 3(d), the standards for grant of product patents on medicines in India would be lower, almost identical to the standards in other countries such as the United States and European Union, where a large number of patents are granted on minor modifications of a single medicine.

The case that is presently before the Supreme Court—*Novartis AG v. Union of India and others*—will most likely decide how section 3(d) is to be applied by the Indian Patent Office when it examines applications for patents for medicines filed by pharmaceutical companies. Will the standard be lowered, as being sought by Novartis AG? Or will the standard be set at a higher level, as being argued by the Government of India, cancer patients and other Indian generic companies?

Thus far, section 3(d) has been used by the Indian Patent Office to deny patents on a several anti-HIV medicines, including the paediatric suspension of *nevirapine hemihydrate*, the heat stable tablet version of *lopinavir/ritonavir* and *tenofovir disoproxil fumarate*. This means that, for now, Indian generic companies can continue to produce these medicines.

Rewriting access history: India takes the lead

In 2001, across most of the world, especially in sub-saharan Africa and Asia and across developing countries, thousands and thousands of people living with HIV were dying. They were dying not because scientists had failed to discover medicines to treat HIV. They were dying because the medicines to treat HIV were available, but only at exorbitantly high prices of over USD 10,000 per patient per year. That was the price that pharmaceutical companies set for each year of life for a person living with HIV. They were able to do this because they owned patents over the medicines (the monopoly right to prevent others from making, using, offering for sale, selling or importing the medicine).

Thus, while HIV became a chronic, manageable condition for those in the developed world who either had the money to pay for it or were covered by insurance or social security schemes, those living with HIV in other parts of the world were condemned to die.

At that time, an Indian generic company offered to make generic versions of these medicines and sell them at USD 350 per patient per year. Over a period of time, other Indian generic companies too entered the market. The consequences were unprecedented. The ensuing competition brought down the prices of the first-line of anti-HIV medicines then in use from USD 10,000 to USD 350 per patient per year. By 2011, the prices of the same anti-HIV medicines were down to USD 61 per patient per year.

How was it possible for Indian generic companies to make and provide these anti-HIV medicines at such low costs? Were these not patented? Well, as described in more detail below, these medicines were not patented in India. By the late 1980s, India had been able to attain self-sufficiency in production of medicines and had started exporting medicines to other countries. So, it was possible for Indian generic companies to make and sell generic versions of the anti-HIV medicines, which were not patented in India.

Rewriting pharmaceutical patent law: India takes the lead

Year of release: 1972

At the time of India's independence, India already had a patent law, the Indian *Patents and Designs Act, 1911*. This 1911 law provided for both product and process patent protection. As documented by Professor Sudip Chaudhuri in his book, *The WTO and India's Pharmaceutical Industry*, this led to monopolies on medicines. The patent-holding pharmaceutical companies would primarily import the medicines into India and sell them at high prices. Prices of medicines in India were amongst the highest in the world.

The Government of India stepped in to address this. In 1970, the Government, under the premiereship of Mrs. Indira Gandhi, introduced a bill in Parliament to amend the existing patent law. Parliament passed the bill and the patent law was amended substantially. (The *Patents Act, 1970* came into force in 1972.) Bearing in mind public health and public interest considerations, the new Indian patent law disallowed product patents on medicines and food. Thus, with respect to medicines, while process patents were permissible, product patents were not to be granted. This meant that no company could obtain an absolute monopoly over medicines.

What are patents?

In India, the *Patents Act, 1970* governs grant of a "patent" to a person who has invented a new product or a new process. A patent is a bundle of "negative" rights that allow the patent holder to stop others from doing certain things.

For instance, if an inventor engages in research and invents a new medicine, s/he can obtain a patent. This "patent" confers certain exclusive rights on the patent holder. On the basis of the patent, the patent holder can prevent others from making, using, selling, offering for sale or importing the patented medicine. No one else can make, use, sell, offer for sale or import the patented medicine without the patent holder's consent.

There are two different types of patents:

- Process patent: A process patent protects only the method (or process) that the inventor has discovered to make the medicine. Only the inventor can use that method to make that medicine. But, this still allows others to make the same medicine using other processes. Therefore, because others can make the medicine using different processes, a process patent grants the patent holder a relative monopoly.
- Product patent: A product patent protects the product that has been discovered by the inventor. Only the inventor can make the medicine. No one else can. Therefore, a product patent grants the patent holder an absolute monopoly.

This right is for a limited period of time. Under the present law (as amended in 2005), this right is granted for a period of 20 years.

By the 1970s, government investment in scientific research had yielded the technical know-how for the development of the domestic industry. The change in the patent law, along with other regulatory changes that favoured domestic investment in the pharmaceutical industry, contributed to the growth of a robust domestic generic industry. In just over a decade, India transitioned from being an importer of medicines to an exporter of medicines.

Rewriting pharmaceutical patent law: India takes the lead—A sequel

Year of release: 2005

In the 1980s, negotiations commenced on establishing a new global trading system. The developed countries, in order to obtain benefits for its multinational corporations, wanted the rules drafted

in a manner that would help them to maximise their profits. To this end, they insisted on the inclusion of intellectual property rights (IPRs), including patents, in the international trade rules in order to establish a global level of intellectual property protection and enforcement standards that all countries would provide. Several developing and least developing countries resisted this push. But, one by one, they were constrained to yield to this demand. However, during the negotiations, India and other developing countries tried to ensure that there would be enough flexibilities within the system that would allow them to cater to their public health and public interest needs when complying with the internationally-mandated global standards for IPRs. The ultimate outcome was the *Agreement on TRIPS Related Aspects of Intellectual Property Rights* (hereinafter referred to as the "TRIPS Agreement"), included as an annexure to the Marrakesh Agreement establishing the World Trade Organization (WTO), which was signed in 1994 and which came into effect from 1 January 1995. The general rule was that countries had to comply with the minimum mandatory requirements set out in TRIPS Agreement by 1 January 1996; transition periods were provided in certain cases.

Now, as a member of the WTO, India was required to provide product and process patent protection for a minimum period of 20 years to inventions in all fields of technology, including medicines and agrochemicals. Countries such as India, which did not provide product patent protection for medicines and agrochemicals, had to amend their laws by 2005 to do so. In the interregnum period, from 1995 to 2005, these countries had to provide a system that would allow inventors to file their patent applications (mailbox applications), which would be examined after 2005. They did not have to examine or grant product patents on medicines until 2005. Further, these countries also had to grant exclusive marketing rights (EMRs) to inventors on satisfaction of three conditions—(i) that the inventor had filed a patent application and obtained a patent in a convention country, (ii) that it had obtained marketing approval in that convention country and (iii) that it had obtained marketing approval in the country under transition. Thus, an EMR was to be granted without an examination of the merits of the patentability of the patent application under domestic law. The EMR would provide the right-holder an exclusive right to market the medicines and prevent others from marketing it.

As mentioned earlier, the period from mid-1990s to early 2000s underscored the impact of product patents on prices of anti-HIV medicines and therefore access to medicines. Data from the United States and other countries had shown that, in contrast to the declining number of new molecular entities that were being approved by drug regulatory authorities, there was a proliferation of patent applications and patents for medicines. Pharmaceutical companies regularly filed for and obtained patents for modifications to existing known substances to either establish monopolies or ensure longer monopoly periods.

Therefore, while amending the patent law to bring it in compliance with TRIPS, India sought to prevent this practice. Concerned about the impact of product patents on medicines, Parliament of India amended the patent law to set higher patentability standards to ensure that only genuine inventions were granted the 20-year monopoly. One such safeguard is the amendment to section 3(d). The 1970 law already excluded certain patenting. For instance, mere discovery of new use or new property of known substances was already excluded from patenting. In 2005, Parliament amended these exclusions contained in section 3 of the *Patents Act, 1970* to also exclude new forms of known substances, unless they exhibited enhanced efficacy.

Relevant Extracts of the Indian Patents Act, 1970 (as amended in 2005)

3. What are not inventions.—The following are not inventions within the meaning of this Act,—

(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

(b) an invention, the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

(c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;

(d) 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**;

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(f) …

(g) …

(h) …

(i) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

(j) …

This amended section 3(d) is what has become the centre of the litigation around the Orange Pill.

The Orange Pill: The Prequel (2003–2005)

The impact of exclusive rights that a product patent confers on a medicine was demonstrated by the Orange Pill even before India amended its patent law in 2005. This took place through the mechanism of an EMR granted to the Orange Pill.

Under the mailbox filing system, Novartis AG filed a patent application in India in 1998 for the beta-crystalline form of *imatinib mesylate*, claiming priority from a similar patent application filed in Switzerland.

In December 2003, Novartis AG obtained an EMR to sell the Orange Pill in India on the basis of a patent granted in Australia, marketing approval granted to its subsidiary in Australia and marketing approval (licence to import) granted to Novartis India by the Drugs Controller General of India. Armed with this EMR, Novartis AG filed suits against nine Indian generic companies to prevent them from selling generic versions of the Orange Pill. Seven of these suits were filed before the Madras High Court and two were filed before the Bombay High Court. The Madras High Court granted an injunction restraining seven generic companies from selling their versions of the medicine. However, the Bombay High Court declined to grant an injunction against two generic companies. Interestingly, to satsify the Madras High Court that public interest would not be affected, Novartis AG modified the criteria for its patient assistance programme. As a consequence of this EMR and court orders, the number of Indian generic producers who were able to supply the medicines declined.

> ***How much did Novartis spend on developing the Orange Pill?***
>
> Publicly available email correspondence dated 2002 with Dr Brian Druker, one of the scientists instrumental in developing the Orange Pill, reveals that "while he was developing the drug, his laboratory's funding sources were:
>
> - 50% National Cancer Institute
> - 30% Leukemia and Lymphoma Society
> - 10% Novartis
> - 10% Oregon Health and Science University"
>
> Source: "A Note on Dr. Brian Druker's Involvement in the Research and Development of Gleevec", *available at* http://www.cptech.org/ip/health/gleevec/drucker.html.

This impacted Cancer Patients Aid Association (CPAA), which procured cancer medicines and provided it at subsidised rates to cancer patients. For chronic myeloid leukemia (CML), prior to the court orders, CPAA could choose between buying Novartis AG's version of the Orange Pill, priced at approximately USD 2,400 per patient per month, and the generic versions, priced at about one-tenth of Novartis' price at between USD 160–240 per patient per month. The EMR granted to Novartis resulted in a reduction of the suppliers for the medicines, thereby affecting access to medicines for cancer patients suffering from CML.

In 2004, CPAA filed a writ petition before the Supreme Court of India challenging the provisions of the law relating to EMR as well as the grant of an EMR to Novartis AG for the Orange Pill on the ground that they violated the fundamental right to health of cancer patients and the fundamental right to equality.

However, before this case could be finally heard, Parliament amended the patent law in 2005. With the Patent Office rejecting Novartis' patent application, the EMR was automatically extinguished. In July 2006, the Supreme Court dismissed the writ petition as having become infructuous.

The Orange Pill: Before the Patent Office (2005–2006)

In 2005, after India changed its patent law, the Patent Office started examining patent applications claiming product patents for medicines. At that time, several Indian generic companies and CPAA filed pregrant oppositions to oppose the grant of a patent to Novartis for the Orange Pill.

They urged that the beta-crystalline form of *imatinib mesylate* was not **new** and was **obvious to a person skilled in the art**. Applying the newly amended section 3(d), they also asserted that a patent ought not to be granted as the beta-crystalline form of *imatinib meyslate* was a **new form of known substances** (*imatinib* and its mesylate salt were known to the public since 1993) and that Novartis had not shown increased efficacy for the beta-crystalline form of *imatinib mesylate*. Other grounds of opposition were also raised.

Novartis denied all these grounds of opposition. In reply to the challenge on the ground of section 3(d), Novartis submitted data to show that the mesylate salt of *imatinib* was more soluble and therefore about 30 percent more bioavailable (more available in the body) than the *imatinib* free base. Novartis argued that this increased bioavailability was sufficient to satisfy the requirement of increased efficacy of section 3(d).

In January 2006, the Patent Office passed an order refusing Novartis' patent application on various grounds. It held that the beta-crystalline form of *imatinib mesylate* was not new and that it did not involve an inventive step. It also held that section 3(d) was applicable to the case and that Novartis had failed to show increased efficacy for the beta-crystalline form of *imatinib mesylate*.

The Orange Pill: Before the Madras High Court (2006–2007)

In June 2006, Novartis approached the Madras High Court and challenged the order of the Patent Office as well as the validity of section 3(d), which was one of the grounds on which the Patent Office rejected its patent application.

In the case challenging section 3(d), Novartis argued that section 3(d) violated Article 14 of the Constitution of India because the term "efficacy" in section 3(d) was vague and the law did not provide guidance on how a patent applicant was to prove enhanced efficacy. This, it claimed, would lead to arbitrariness and therefore violate Article 14 of the Constitution of India. It also argued that section 3(d) violated India's international obligations under TRIPS.

Responding to these challenges, CPAA argued that the term "efficacy" was well-known in the pharmaceutical field and had a particular meaning, i.e. the ability of the medicine to produce an effect. CPAA urged that, as the term "efficacy" was not vague, section 3(d) was not arbitrary and did not violate the equality clause. In response to Novartis' argument that section

3(d) was violative of the TRIPS Agreement, CPAA questioned the standing of Novartis—a private body—to raise this dispute. CPAA pointed out that, because TRIPS is a multilateral treaty with a specific dispute resolution mechanism that allowed only member States (governments) to raise disputes, it was not open to Novartis to raise this issue. It was also pointed out that it was not open to domestic Indian courts to explore the issue of whether domestic Indian law was compliant with the TRIPS Agreement.

Glivec International Patient Assistance Programme (GIPAP)

Before the Madras High Court, in 2006, Novartis claimed that it was providing 99 percent of *Gleevec* (Novartis' brand), the Orange Pill, free of cost to patients suffering from CML in India under its patient assistance programme—Gleevec International Patient Assistance Programme (GIPAP) and sold only one percent of its drug. The criteria set for enrollment under GIPAP were: "(i) the patient should have been properly diagnosed, (ii) the patient is earning less than INR 3,36,000 (*USD 6720*) per month, (iii) the patient does not have insurance cover; (iv) the patient is not being reimbursed by the employer or the Government and / or (v) the patient is otherwise not being compensated".

Interestingly, in December 2004, while resisting the appeals filed by seven generic companies challenging the *ex parte* injunction granted to Novartis based on its EMR, Novartis undertook to change some of the existing GIPAP criteria in order to satisfy the court that the public interest of access to medicines would not be affected. Novartis gave an undertaking that, for patients who are entitled to insurance or reimbursement schemes and hospitals, it would provide any shortfall in the amount for the treatment that the insurance or reimbursement did not cover. The Madras High Court also directed Novartis to file a monthly compliance report in the Court of this arrangement to supply medicines. During the course of the cases in which Novartis challenged the Patent Controller's order and section 3(d), Novartis submitted data to show that, as of 15 August 2006, GIPAP covered 5821 CML patients.

However, CPAA also had experienced working with GIPAP. Patients were required to undergo progression of treatment from hydroxyurea to interferon and were offered *Gleevec* only if they failed these prior lines of regimen. Even after this, patients were denied access to *Gleevec*. CPAA also pointed out that even labourers were ineligible for access under GIPAP because they were ostensibly covered by government and employer-sponsored insurance schemes, which, in fact, did not reimburse costs of treatment of diseases such as CML.

CPAA also filed the affidavit of Dr. Purvish Parikh, a Professor and Head, Department of Medical Oncology, Tata Memorial Hospital, Mumbai. He pointed to various instances which gave rise to concerns about ethical issues relating to GIPAP. He also pointed out that some CML patients, who required treatment and who were referred by him to GIPAP, had, in fact, been rejected by GIPAP.

In a judgment delivered in August 2007, the Madras High Court rejected all of Novartis' arguments. Citing scientific literature that defined the term "efficacy" to mean "the ability of the drug to produce the desired therapeutic effect", it held that the term "efficacy", as used in section 3(d), is not vague. The Madras High Court also refused to decide the question as to whether section 3(d) is TRIPS-compliant on the ground that the WTO Dispute Settlement Panel, and not the domestic court, was the proper forum to decide this issue.

> *"We have borne in mind the object which the Amending Act wanted to achieve, namely … to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens."*
>
> *—Novartis AG and another v. Union of India and others*, Madras High Court, Writ Petition Nos. 24759 and 24760 of 2006, Judgment dated 6 August 2007

Novartis did not challenge the Madras High Court's judgment before the Supreme Court of India.

The Orange Pill: Before the Intellectual Property Appellate Board (2007–2009)

In 2007, the second set of cases challenging the order of the Patent Office rejecting Novartis' patent application were transferred by the Madras High Court to the Intellectual Property Appellate Board (IPAB).

In June 2009, the IPAB delivered its order. It overturned the Patent Office's findings on all issues except section 3(d). It accepted Novartis' arguments and held that the beta-crystalline form of *imatinib mesylate* was new and involved an inventive step.

FINDINGS ON GROUNDS OF OPPOSITION		
	Patent Controller's Order	**IPAB Order**
Novelty	Not established (×)	Established (✓)
Inventive Step	Not established (×)	Established (✓)
Section 3(d)	Not established (×)	Not established (×)
Priority	Wrongly claimed (×)	Properly claimed (✓)

However, it held that Novartis had not shown that the beta-crystalline form of *imatinib mesylate*, a crystalline form of *imatinib mesylate* (which was a known substance), was more efficacious than *imatinib mesylate*. It held that, in order to satisfy section 3(d), a patent applicant had to show increased efficacy and that section 3(d)'s standard is not satisfied by a showing of increased bioavailability or improved stability, storability or flow properties.

Thus, as Novartis had failed to satisfy section 3(d), the IPAB upheld the Patent Office's order and rejected Novartis' appeal.

The Orange Pill: Before the Supreme Court (2009–present)

Later that year, Novartis approached the Supreme Court and filed a special leave petition to challenge the IPAB's order.

Novartis is arguing that section 3(d), which relates to new forms of known substances, does not apply to its patent application at all. Novartis also argues that if section 3(d) does apply, Novartis' data on increased bioavailability and stability should be accepted as proof that the Orange Pill, i.e. beta-crystalline form of *imatinib mesylate*, shows increased efficacy. CPAA and Natco Pharma Ltd., a generic company, have filed cross petitions challenging the IPAB's findings on other issues.

The Supreme Court will now start hearing Novartis' petition in July 2012 to decide how section 3(d) is to be interpreted and applied in India to new forms of already known substances.

A judgment delivered by the Supreme Court on these issues—whether section 3(d) is applicable to patent applications such as the beta-crystalline form of *imatinib mesylate* and the meaning of "efficacy"—will become the law of India. In all pending and subsequent cases, the Patent Office in India, the IPAB and the High Courts will apply these standards to decide whether patents, i.e. 20-year monopolies, ought to be granted to new forms of already known substances.

If India, too, as other countries, allows patents on new forms of already known substances, the patent-holding pharmaceutical company will be able to prevent other competitors from entering the market. For medicines that were invented before 1995, before India incurred obligations under the WTO-mandated TRIPS Agreement, it means that pharmaceutical companies can still obtain monopolies and prevent generic competition by obtaining patents on new forms of these pre-1995 medicines. For medicines invented after 1995 and where a patent may have been granted on the discovery of a truly new medicine, it means that pharmaceutical companies can file multiple patent applications, one after another, and "evergreen" their monopolies for a period that would extend beyond the 20-year patent of the first patent on the new medicine.

Either way, when the curtains come down on what may be the final act of the Orange Pill, it will have rewritten history once again.

Hearing Update

The final hearing of Novartis' petition and related cases will commence before the Supreme Court of India on 10 July 2012.

OTHER CHALLENGES TO SECTION 3(d)

The threat that any newly identified bug is perceived to pose to public health can often be gauged by the resources deployed against it. By that standard, the threat that section 3(d) is perceived to pose to private commercial interests can probably be gauged by the multiple fronts that have been opened up against section 3(d).

In the past seven years since its enactment, section 3(d) has met a fair share of opponents, both in India and internationally. Attempts to challenge section 3(d) are not confined to courts. A full-fledged advocacy campaign is underfoot to get India to amend its patent law as well as to ensure that other countries do not follow the same trend.

In a bid to discredit section 3(d), opponents of section 3(d) portray it as a provision that disallows "incremental innovation". What is termed by public health advocates as "evergreening", the attempt to obtain patents on routine modifications to known substances and thereby extend patent monopolies, is termed by pharmaceutical companies and their allies as "incremental innovation".

Apart from this, there are also attempts to dilute section 3(d) by seeking to get section 3(d) interpreted in a manner that would allow patents on salts, esters, polymorphs, combinations, etc of known substances.

Below we list out some of the major instances where section 3(d) has been assailed. Co-incidentally, some of these have occurred at different stages of pending litigation involving section 3(d).

Report of Technical Expert Group—The Mashelkar Report (2005–2006, 2007–2009)

While the patent law was being amended in 2005 to provide product patents for medicines, some were of the view that India should further raise the bar of patenting for medicines. It was proposed that product patents on new medicines should be granted only to new chemical entities, a standard that would raise the bar even above section 3(d). Because of concerns of TRIPS-compliance, the Government of India referred this question (and the question of exclusion of microorganisms from patenting) to a Technical Expert Group, headed by Dr. R.A. Mashelkar.

Several interested parties, including public interest groups and pharmaceutical companies, made written and / or oral submissions to the TEG. [You can read excerpts of the written submissions of *Affordable Medicines and Treatment Campaign* in our earlier newsletter, *Access*, January 2006, vol I, issue 3].

In December 2006, the TEG submitted its report to the Government (2006 Report). The TEG opined that restriction of patenting of medicines only to new chemical entities and a *per se* exclusion of microorganisms from patenting would not be compliant with TRIPS. Interestingly, to reason its stand on the issue of patenting of medicines, the 2006 Report did not provide a legal analysis, but cited how it would be adverse to the interests of the "national" pharmaceutical industry. Even more surprisingly, despite the fact that the TEG's opinion had not been sought on the already enacted section 3(d), the TEG Report noted that there was a perception that even India's

decision to disallow patenting on new forms of known substances through section 3(d) was not TRIPS-compliant.

The timing of the submission of the TEG Report and its contents proved to be a boon for Novartis in its case before the Madras High Court challenging the TRIPS-compatibility and constitutional validity of section 3(d). As hearing commenced before the Madras High Court in January 2007, counsel for Novartis AG filed the TEG's 2006 Report. Citing the comments of the TEG on the importance of patent protection for "incremental innovation" and the references to section 3(d), Novartis' counsel demanded that the Government of India make its stand on the TEG Report—known to the court. The matter was adjourned for a few weeks to allow the Government to submit its stand.

In February 2007, a few weeks later, before the next hearing, editorials published in two major publications— *The Hindu* and *The Times of India*—revealed that a substantial portion of the 2006 Report was plagiarised and copied verbatim from an industry-funded report. The report, which had been authored by Shamnad Basheer, acknowledged funding for the submissions from INTERPAT, an association of major multinational pharmaceutical companies, including Novartis AG.

We then wrote to the Government of India asking it to reject the 2006 Report and constitute another TEG.

About a week after the publication of the newspaper editorials, Dr. Mashelkar reportedly wrote to the Government of India and withdrew the 2006 Report citing certain "technical inaccuracies" that had crept in the "initial drafts attempted by a drafting sub-group" and that were "not detected in time".

These developments led to Novartis' counsel deciding to drop its reliance on the 2006 Report.

Strangely, instead of constituting another TEG, the Government allowed Dr. Mashelkar to submit a revised Report.

About two years later, the TEG re-submitted its Report (2009 Report). Not unsurprisingly, the 2009 Report too contained the same findings—that it would not be TRIPS-compliant to restrict patenting of medicines only to NCEs—although with a re-worded justification. The revised 2009 Report justified the conclusion of the 2006 Report by citing a report by South Centre titled "Integrating Public Health Concerns into Patent Legislation in Developing Countries". Interestingly, on the release of the 2009 Report, the author of the South Centre Report said that the South Centre Report had been misinterpreted by the TEG.

Expressing our concerns about the credibility of the 2009 Report, we wrote to the Government again asking it to reject the 2009 Report. However, we did not receive a reply.

Nonetheless, the timely disclosure of the plagiarism and the subsequent withdrawal of the 2006 Report prevented it from being used in the legal challenge against section 3(d). For now, the *status quo* is maintained. Section 3(d) remains on the statute book, but the Government has, since then, not taken steps to further raise the patentability bar for medicines.

USIBC Report (June 2009)

Industry, including the pharmaceutical industry, has long engaged in advocacy and lobbying to secure their interests. Drawn together by the common goal of securing commercial interests, top private companies in India and the United States (US) have set up an advocacy organisation called the United States India Business Council (USIBC).

USIBC boasts of a membership that includes several US pharmaceutical companies, including Abbott Laboratories, Gilead, Merck, Novartis and Pfizer. Ranbaxy, too, is a member of USIBC. With such a membership, it would stand to reason that USIBC, too, has a stand on section 3(d). Well, it does. It would like India to remove or amend section 3(d).

For several years now, USIBC has been publicly advocating against section 3(d).

In 2009, USIBC published a report "The Value of Incremental Pharmaceutical Innovation: Benefits for Indian patients and Indian businesses" on section 3(d). Claiming that patents on "incremental innovations"—modifications of known substances—was, in fact, beneficial for patients and could lead to decreased costs and increased access to medicines as well as prove beneficial to domestic pharmaceutical industry, the Report recommended the removal of section 3(d) completely.

This report, which makes several references to the Novartis case, was published in June 2009, after the IPAB had concluded hearings of Novartis' appeal against the Patent Office's decision and just a few weeks before the IPAB issued its decision on 26 June 2009.

Since then, section 3(d) continues to be on the agenda of USIBC.

For instance, USIBC's 2011–2012 as well as 2012–2013 Business Advocacy Agenda includes advocacy "for the Government of India to adopt a more nuanced definition and interpretation of Section 3(d) of India's Patents Act such that member companies can achieve intellectual property protections for incremental innovation".

It appears that USIBC's advocacy has, for its final goal, an amendment of section 3(d) that would allow pharmaceutical companies to obtain patents in India just as it does in other countries.

Apart from section 3(d), USIBC also resists drug price control measures and compulsory licensing and advocates for data "protection" for the biotech industry and patent linkage.

USTR on Section 3(d)

Leaked cables on Wikileaks indicate that it is not only private industry that is concerned about section 3(d).

Officials of the office of the United States Trade Representative (USTR) are concerned about section 3(d) and its use by the Indian Patent Office to reject patent applications.

In 2009, the Indian Patent Office rejected patent applications filed by Gilead Sciences, Inc. relating to *tenofovir disoproxil* and

tenofovir disoproxil fumarate. One of the grounds on which the patent applications were rejected was section 3(d)—that the claimed forms were new forms of already known substances [*tenofovir*, the basic molecule, had been discovered in the 1980s] and the patent applicant had not shown an increase in efficacy.

A leaked cable reveals that section 3(d) was discussed during a meeting in October 2009 between the officials of the USTR's Office and the Government of India. Concerns were raised about the rejection of "Gilead's patent application for incremental innovations". The cable noted that, after a discussion that focussed on "Gilead's rejected patent applications for "incremental innovations", "both sides agreed that it was advantageous to patent incremental innovation and, in Gilead's case, that appropriate procedures, such as review appeal, under the Indian Patent Act would be followed". Further, as per the cable, both sides would also continue discussion on the scope of patentable subject matter and decisions of the Indian patent office under section 3(d).

This was not an isolated instance.

Newspaper reports revealed that, in November 2010, the US Commerce Secretary sent a letter to the Indian Commerce Minister to once again raise the issue of the Indian Patent Office's rejection of Gilead's patent applications. Asking India to "fully consider the requisite business climate for spurring innovation, especially intellectual property protection", the US Commerce Secretary noted that the Indian Patent Office's rejection of Gilead's patent applications was contrary to the decisions of patent offices of other countries, including the US.

Free Trade Agreements

Apart from this, the US is also pushing to ensure that other countries do not adopt a law similar to section 3(d).

Several countries, including Australia, Chile, Peru, US and Vietnam, are presently negotiating the *Trans-Pacific Partnership Agreement* (TPPA), a multilateral free trade agreement. Similar to the Agreement establishing WTO and other free trade agreements, there is a proposal to include a chapter on IPR.

Leaked text of drafts of the IPR chapter of the TPPA proposed by the US discloses that the US is proposing a clause that would require countries not to disallow patents on new forms of known substances or impose a requirement of showing of efficacy.

While not a party to the negotiations, the Government of India has still voiced its objections to the inclusion of this and other clauses in the TPPA. Such clauses would effectively end up isolating India globally on the public health safeguards in the patent law and allow additional pressure to be exerted on India to change its law to bring it in line with that of other countries.

This is especially relevant as the Government of India too is negotiating trade agreements and investment agreements with other developed countries. It is likely that these developed countries, including countries belonging to the European Free Trade Association, will demand that India change its patentability standards. While we hope that the Government of India will continue to oppose these demands, the fact that these agreements are negotiated in secret means that the public is denied the opportunity of voicing its concerns and demonstrating its support to the Government of India's opposition to these demands.

Conclusion

Even as the Government of India publicly defends section 3(d) before the courts in India and at other international fora, it cannot be denied that considerable pressure is being brought to bear on the Government of India to amend or delete section 3(d).

As the Government of India engages in firefighting to defend section 3(d) on various fronts, it must also now take the war to the opponents.

For nearly two decades, developing countries have been working within the paradigm of TRIPS. At least from 2005, developing countries have amended their IP laws to provide for increased IP protection, as mandated by TRIPS. But, the promises of increased investment and transfer of technology have not been fulfilled. There is no evidence thus far that shows that increased IP protection has led to increased innovation or research and development. On the other hand, developing countries are being pressured to accept TRIPS-plus IPR protection and enforcement standards through trade agreements.

Given this, attempts to lower the bar of patentability standards should be countered with a move to further raise the bar of patentability standards and a strict implementation of domestic patentability standards in the Patent Office.

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