WTO, Compulsory Export Licences and Indian Patent Law

by

Hafiz Aziz ur Rehman *

* Hafiz Aziz ur Rehman is currently a PhD Candidate at ANU College of Law, the Australian National University, Australia. He is an Assistant Professor at the Faculty of *Shariah* & Law, International Islamic University, Islamabad. He holds Masters in European Intellectual Property Law (LLM) degree from Stockholm University, Sweden. He can be reached at: azeez.rehman@gmail.com. I am specifically thankful to my supervisor, Dr. Matthew Rimmer, for his valuable comments and suggestions. All errors and omissions are, however, mine

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Injurious Commissions also include severely restrictive – and inefficient – trade barriers that curb exports from poorer countries.

Amartya Sen, *Identity and Violence*[1]

I. Introduction

A 2005 publication of UNAIDS, *AIDS in Africa: Three Scenarios to 2025*, contains several moving stories about HIV/AIDS in Africa, describing how the AIDS epidemic in Africa could evolve over the next 20 years.[2] The scenarios set out to answer one central question: over the next 20 years, what factors will drive Africa's and the world's responses to the AIDS epidemic, and what kind of future will there be for the next generation? Amongst the various aspects of the problem, access to and uptake of AIDS treatment is discussed and highlighted throughout the document. The publication highlights how crucial Indian pharmaceutical exports are for the treatment of the HIV/AIDS epidemic in Africa.

African nations and many other developing countries require access to essential medicines to address public health concerns. The creation of a safe, secure and reliable access to an essential medicines regime depends upon a number of factors ranging from mobilisation of resources to administration of drugs to those who badly need them in extreme poverty situations. Factors such as resources prioritisation, adequate procurement policies, supporting infrastructure and trained personnel are definitely very crucial for any successful essential drugs program. However, the most critical factor is the very availability of the medicines which could then be provided to those who need them. The most crucial and the daunting barrier increasingly faced in this regard is the accessibility to safe and affordable medicines to keep up the life expectancy trajectory of millions of poor patients around the world.

According to available research, Indian generic pharmaceutical companies provide a major portion of pharmaceutical products which are procured by various international and regional organisations for their treatment projects related to HIV/AIDS, malaria and tuberculosis.[3] The

[1] Amartya Sen, *Identity and Violence* (New York: W.W. Norton & Company, 2006) 140.

[2] United Nations Programme on HIV/AIDS (UNAIDS), *AIDS in Africa: Three scenarios to 2025*, 2005 at http://www.unaids.org/unaids_resources/images/AIDSScenarios/AIDS-scenarios-2025_report_en.pdf.

[3] Padmashree Hehi Sampath, 'Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry' (Accessed on July 12, 2009) Institute of New Technologies, United Nations University at http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf.

following table shows the list of top ten suppliers of Antiretroviral (ARV) drugs under the Global Fund's procurement program.

Table 1.1: Top Ten Suppliers of ARVs under Global Fund in Terms of Consignments (June 2003-Jan 2006)

Manufacturer	Total No. of Consignments
Cipla Ltd.	342
Aspen Pharmacare	221
Bristol Myers Squibb	158
GlaxoSmithKline Ltd.	144
Abbott Laboratories	88
Merck	73
Ranbaxy Laboratories	45
Hetro Drugs Ltd.	35
Roche	32
Boehringer Ingelheim	25

Source: Global Fund as cited by Biswajit Dhar[4]

Table 4.1 shows that although four Indian firms are among the top ten suppliers by volume, in terms of value only two appeared in the top ten, because of their lower prices.[5] Another source cites the data of Global Fund's suppliers in terms of brand names and generics. It shows that in 2004, brand name, patented, manufacturers supplied 40.7% of total procurements by volume but their share in expenditure terms was around 53%, whereas, generic manufacturers supplied almost 59.3% of the volume of total drugs with only a 47% share of expenditures.[6] Other international humanitarian agencies like UNICEF and the Clinton Foundation rely heavily on importing affordable drugs from India. Indeed 84% of the ARVs that *Médecins Sans Frontières* prescribes to its patients worldwide come from Indian generic companies.[7]

There has been much debate as to whether India will be able to continue to be such a dominant supplier of generic medicines, in an era where it must be compliant with the *TRIPS*

[4] Biswajit Dhar and K.K. Gopakumar, 'Post-2005 TRIPS scenario in patent protection in the pharmaceutical sector: The case of generic pharmaceutical industry in India' (2006), UNCTAD, IDRC and ICTSD, 57 at http://www.measwatch.org/autopage/file/MonMarch2009-14-25-16-IndianINDUSTRY.pdf.

[5] Ibid. 56.

[6] Kenneth C. Shalden, 'The Political Economy of AIDS Treatment: Intellectual Property and the Transformation of Generic Supply' (2007) 51 *International Studies Quarterly* 559-581, 564.

[7] Gustavo Capdevila, 'Indian court rejects Novartis' drug patent suit' Asia Times online, 8 August 2007, http://www.atimes.com/atimes/South_Asia/IH08Df01.html.

Agreement 1994. Several studies consider whether compulsory licensing will be an effective tool to maintain the current level of supplies from Indian generic manufacturers.[8] We can see four different strategies bearing on the relevancy and usefulness of compulsory licensing as a means of providing access to medicines. First of all, multinational brand-name pharmaceutical companies represented by Pharmaceutical Research and Manufacturers of America (PhRMA) have favoured a narrow and limited scope for compulsory licensing mechanisms. Accordingly, this industry is largely comfortable with the *Waiver Decision 2003* and the way in which limitations and restrictions are imposed on the issuance of compulsory licences. Second, a number of academics and commentators contend that the compulsory licensing arrangements under the *Waiver Decision 2003* will have a positive impact on pharmaceutical export mechanisms. Scholars like Frederick Abbott and Jerome *H.* Reichman belong to this group when they argue that export mechanisms can be boosted through a well-designed implementation strategy.[9] Third, civil society groups such as *Médecins Sans Frontières (MSF) and* Knowledge Ecology International (KEI) hold critical positions about the negative implications of *the Waiver Decision 2003* on export mechanisms. They argue that the complicated and cumbersome procedure envisaged under the *Waiver Decision 2003* will inevitably limit the ability of export markets to meet the demands of poor and developing countries. Finally, there is a group of commentators who contend that the *Waiver Decision 2003* has a symbolic significance, even though its practical, tangible impact is negligible. Employing the themes of rule complexity and regulatory ritualism, Professor Peter Drahos has highlighted the limitations of the *Waiver Decision 2003* to show the futility of outcome.[10]

This chapter contends that the compulsory licensing mechanism for exports under the *Waiver Decision 2003* lacks efficacy. It argues that the Indian compulsory licensing regime fails to facilitate affordable drug supply to other developing countries, because of the rigidity and complexity of treaty rules; economic considerations; technological constraints and capacity; and a fickle lack of political commitment. The main hypothesis extended is that without a viable, affordable and continuous generic supply from India, the success of *Doha Declaration 2001*

[8] See for example: Biswajit Dhar and K.K. Gopakumar, 'Post-2005 TRIPS scenario in patent protection in the pharmaceutical sector: The case of generic pharmaceutical industry in India' (2006), UNCTAD, IDRC and ICTSD, 56; Alka Chadha, 'Product Cycles, innovation and exports: A Study of Indian pharmaceuticals' (2005), Department of Economics, National University of Singapore Working Paper No. 0511 at http://www.fas.nus.edu.sg/ecs/pub/wp/wp0511.pdf. Also see: Padmashree Gehl Sampath, 'Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry' Institute of New Technologies, United Nations University at http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf.

[9] Frederick M. Abbott and Jerome H. Reichman, 'The Doha Round Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions' (2007) 10(4) *Journal of International Economic Law* 921-987, 941.

[10] Peter Drahos, 'Four Lessons for Developing Countries from the Trade Negotiations over Access to Medicines' (2007) 28(11) *Liverpool Law Review* 39 at http://www.anu.edu.au/fellows/pdrahos/pdfs/2007fourlessonsfordevcountries.pdf.

would be substantially compromised. Part II of this chapter deals with the key provisions in the *TRIPS Agreement 1994* dealing with the exports of pharmaceutical drugs. Part III considers the *Doha Declaration 2001* and the subsequent *Waiver Decision 2003*. Part IV considers the various species of compulsory licensing under Indian patent law. Part V considers the first Indian compulsory licensing instance under the new law and the Natco's application for the grant of compulsory licences of erlotinib and sutent.

II. The TRIPS Agreement 1994 and Pharmaceutical Exports

Before the adoption of the *TRIPS Agreement 1994*, developing countries were largely free to determine the scope, term and availability of patent protection as a part of their overall industrial and public health policy objectives. Although many developing countries were members of the *Paris Convention for the Protection of Industrial Property of 1883 (Paris Convention 1883)*, they retained the flexibility to legislate on domestic pharmaceutical production and access to essential medicines. In terms of substantive rule-making, patentable subject matter, local usage and enforcement measures, the *Paris Convention 1883* leaves considerable space for Member States to devise and implement their own patent systems. Indeed, it even allows Member States to deny protection for certain subject matters such as pharmaceutical products.

However, under the *TRIPS Agreement 1994*, all Member States are now required to comply with the minimum standards set out in the treaty. The obligations of the *TRIPS Agreement 1994* include the extension of patent protection to all qualifying inventions without the discrimination of any field of technology and origin of subject matter.[11] Thus the developing countries were obligated to extend patent protection to pharmaceutical products pursuant to the requirements of the *TRIPS Agreement 1994.* Since the expiry of the limited transition period in 2005, the situation has radically changed in developing countries and they have introduced new laws and governing regulations dealing with the patentability of medicines and related components. In 1994, India decided to take advantage of the transitional period allowed under the *TRIPS Agreement 1994* for developing countries, which ultimately ended in 2005.

The *TRIPS Agreement 1994* recognises the right of member countries to issue compulsory licences subject to procedural requirements laid down in Article 31. However, the option of invoking Article 31 flexibilities to meet public health objectives had no real meaning for many developing and least developing countries because they lacked any local pharmaceutical manufacturing capabilities. The problem is directly linked with the language of Article 31(f) of the *TRIPS Agreement 1994* which, after initially allowing the grant of a compulsory licence, restricts the operation of this option by stating:

[11] Article 27.1 of the *TRIPS Agreement 1994.*

> (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

However, in practice, many developing and least developing countries lacked sufficient manufacturing capacity for the production of highly advanced and technologically sophisticated medicines to address public health epidemics. They did not have even a possibility of getting cheaper medicines from India, China or Brazil under a compulsory licence because any such production in these countries was supposed to be predominantly for the supply of the local market and only a fraction of total produce was allowed to be exported to the countries which mainly needed these drugs.

The WTO Ministerial Conference adopted the *Doha Declaration 2001*[12] in November 2001. This was the product of an extensive lobbying effort of international humanitarian organisations, NGOs and the governments of developing and least developing countries. The *Doha Declaration 2001* reaffirmed the flexibilities built into the *TRIPS Agreement 1994*, including the right of Member States to issue compulsory licences on public interest grounds.[13] The Declaration then specifically addressed the problem of Member States lacking the capacity to manufacture cheaper generic substitutes and which are otherwise not capable of exploiting the flexibilities under the existing Article 3(f) requirement. Paragraph 6 of the *Doha Declaration 2001* mandated the relevant WTO body to work out a suitable solution, keeping in view the limitations of such countries with an aim to ensure access to essential medicines.[14]

After almost two years of extensive discussions at WTO a solution, initially embodied in the form of a Waiver, was reached on 30 August 2003 (*Waiver Decision 2003*).[15] In the light of various proposals and discussions, it was decided that this *Waiver Decision 2003* would be rendered as permanent in the form of an amendment to the *TRIPS Agreement 1994* as Article 31*bis*.[16] The ratification of the proposed amendment is still pending while Member States consider their options. Meanwhile the waiver reached on 30 August 2003 is effective and would continue to operate. The *Waiver Decision 2003* and the *Protocol amending the TRIPS Agreement 1994* are summarised in the following section along with a brief analysis of some provisions.

[12] *Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (14 November 2001) at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[13] Ibid. Paragraph 5(b).

[14] bid. Paragraph 6.

[15] *Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (30 August 2003) (Decision of the General Council of 30 August 2003) at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[16] *WTO General Council Decision of 6 December 2005 Amendment of the TRIPS Agreement*, WT/L/641, (8 Dec. 2005) (Protocol Amending the TRIPS Agreement' with Annex setting out Article 31bis) at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

III. The Waiver Decision and Proposed Article 31*bis*

In 2001, paragraph 6 of the *Doha Declaration 2001* recognised that the countries with limited or virtually no manufacturing capacity in the pharmaceutical sector had difficulties in invoking the compulsory licensing mechanism set out in Article 31 of the *TRIPS Agreement 1994*. Subsequently based upon the mandate of the *Doha Declaration 2001,* the WTO General Council's *Waiver Decision 2003* paved the way to allow countries with sufficient manufacturing capacity to make and export pharmaceutical products to countries which require such medicines for public health needs. This objective is achieved through a mechanism whereby restriction of Article 31(f) is waived for the exporting countries (by relaxing the requirement of manufacturing predominantly to the supply of domestic market), and restriction of Article 31(h)[17] is waived for importing countries. Proposed Article 31*bis* essentially reflects the terms of the *Waiver Decision 2003* by establishing the waiver of certain obligations of the *TRIPS Agreement 1994* as mentioned earlier.

A. Scope and Coverage of Diseases

Paragraph 1 of the *Waiver Decision 2003* defines 'pharmaceutical product' broadly without limiting application of the solution to certain specific diseases. It reads:

> (a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.[18]

The definition is sufficiently broad as active pharmaceutical ingredients (APIs) and diagnostic kits are expressly covered. The definition is also sufficiently broad to cover vaccines because vaccines are 'products of the pharmaceutical sector'.

The negotiations prior to the adoption of *Waiver Decision 2003* were quite extensive with regard to the scope and coverage of diseases to be covered under the proposed mechanism. The United States proposed to restrict the candidate list of diseases to HIV-AIDS, malaria, tuberculosis and a relatively small group of infectious diseases. The US proposal also sought to limit the countries that would benefit from the solution and considered it to be the Ministers'

[17] Remuneration requirement is explicitly waived. This aspect is discussed further hereafter.

[18] *Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (30 August 2003) (Decision of the General Council of 30 August 2003) Paragraph 1 at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

intention at Doha.[19] At some later stage of negotiations, the EC had demonstrated a relatively more flexible approach and suggested that the solution be confined to grave public health problems and a potential role of WHO was also mentioned to identify such grave situations.[20] On 28 January 2003, India together with several developing countries submitted that they would not accept the USA and EC proposals as they would narrow down the scope of paragraph 1 of the Doha Declaration.[21]

India's position prevailed. Paragraph 1 of the *Doha Declaration 2001* does not mention any limitation on the application of the Declaration to certain specific diseases or medicines and the position of developing countries was finally reflected in the *Waiver Decision 2003*. The proposed Article 31*bis* mirrors this stance.

B. Notification Requirement and Eligible Countries

Both the *Waiver Decision 2003* and the proposed Article 31*bis* contemplate two important notification requirements. The first is a general notification of intent which is required from all member countries that use the system, other than least developing countries.[22] The group of members belonging to least developing countries are thus free to invoke the mechanism without any notification of intent. Both the instruments also provide that any Member State may notify the *TRIPS Council* that it does not intend to use the system as an importing country or that it only intends to use it in a limited way. Almost all OECD countries have practically opted out by notifying their intention not to use the system or to use it in a limited way.[23] A number of Member States (Hong Kong, China, Israel, Kuwait, Macao Chian, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and the United Arab Emirates) notified their intention to use the system only in cases of national emergency or other circumstances of extreme urgency.[24] By analogy, one can construe that other non-notifying Member States may then use the system liberally in situations other than national emergency or circumstances of extreme urgency.

[19] Cecilia Oh, '*Developing countries criticise attempts to limit scope of diseases in Paragraph 6 negotiations*', Update on 5 Feb 2003 informal meeting of TRIPS Council and Background to the Negotiations on Para 6, Page 4. at http://www.twnside.org.sg/title/TRIPS-Feb5.doc.

[20] Ibid.

[21] Ibid. 3

[22] Paragraph 1(b), *WTO General Council Decision of 6 December 2005 Amendment of the TRIPS Agreement*, WT/L/641, (8 Dec. 2005) (Protocol Amending the TRIPS Agreement' with Annex setting out Article 31bis) at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

[23] Ibid. Footnote 3 to Paragraph 1(b).

[24] Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) 7(1) *Journal of International Economic Law* 73-107, 95.

On 19 July 2007, Rwanda became the first WTO Member State which notified its intention to use the system to import some 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine and Nevirapine, from a Canadian pharmaceutical firm Apotex, Inc.[25] It is pertinent to note that Rwanda had no obligation to notify as such being a designated least developing country and it was eligible to use the system without following any procedural formalities. However, a notification requirement is imposed upon the potential exporting WTO Member States pursuant to paragraph 2(c) of the *Waiver Decision 2003*. In response to the request of Rwanda, the Canadian Government notified the TRIPS Council of the terms of the export licence it had issued in this regard.[26] Some commentators have criticised the elaborate and lengthy procedural notification procedure in the Canadian regime.

C. Determination of Manufacturing Capacity

According to Article 31*bis* least developing countries are automatically eligible to import medicines under the system envisaged in this regard. In addition to this, any country making a determination that it has insufficient or no manufacturing capacity of a particular pharmaceutical product, can also become an eligible importing state.[27] This Article further provides that the determination of manufacturing capacity in this regard by the importing country excludes the production facilities which are owned or controlled by the patent holders. It states:

> Where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.[28]

The language of the Article 31*bis* about the definition of pharmaceutical product and determination of manufacturing capacity would be helpful for a developing country that wants to use this system merely to import pharmaceutical products to manufacture medicines locally for justified public health needs.

[25] *Rwanda- Notification under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/N/9/RWA/1 (19 July 2007) at http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm.

[26] *Canada-Notification under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, , WTO Doc IP/N/10/CAN/1 (18 October 2007) at http://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm.

[27] Paragraph 2(a) (ii), *WTO General Council Decision of 6 December 2005 Amendment of the TRIPS Agreement*, WT/L/641, (8 Dec. 2005) (Protocol Amending the TRIPS Agreement' with Annex setting out Article 31bis) at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

[28] Ibid. Appendix to Annexure.

D. Licensing Scheme

Both the *Waiver Decision 2003* and proposed Article 31*bis* detail the procedural and substantive requirements that deal with the issuance of compulsory licences by importing and exporting countries.

As an importing country, members from least developing countries are entitled to use the system without meeting any notification requirement. Thus, these countries can use the system without issuing domestic compulsory licences which is otherwise required under the scheme. Likewise, any other Member State, where the desired medicine is not patented, can also use the system without issuing a compulsory licence. In all other cases, countries which are willing to use this system must issue a compulsory licence prior to importation and it must notify the *TRIPS Council* of such intention.[29] The conditions which are generally set out in Article 31 of the *TRIPS Agreement 1994* should be complied with while the countries consider the option of issuing compulsory licence. So the solution evolved through the *Waiver Decision 2003* and the proposed Article 31*bis* should be construed and applied in conjunction with other substantive requirements of the *TRIPS Agreement 1994* unless specifically waived. The issuance of a compulsory licence itself entails several procedural and administrative complications within the overall scheme of the *TRIPS Agreement 1994* and it has yet to be seen how developing countries will overcome those legal and administrative barriers to implement the *Waiver Decision 2003* in an effective and efficient way. However, Article 31 does not attempt to limit in any way the grounds upon which compulsory licences may be issued and its procedural requirements can be incorporated in domestic legislation in a way which would supplement the flexibilities designed under Article 31*bis*.

Article 31*bis* also suggests some disclosure obligations on importing country in terms of identification of product(s) and expected quantities to be imported. This should be notified to the *TRIPS Council*.[30] This aspect has been specifically criticised by some commentators for being too restrictive and inhibitive as an exact determination of expected quantity can be unviable both practically and economically. Furthermore, no model exists to satisfy such procedural requirements and it may put the willing Member States in an unending exercise of monitoring and evaluation.[31] Some commentators do not consider it a critical obstacle and suggest that the proposed Article 31*bis* does not demand a particular fixed formula, and there are various possibilities for complying with this obligation in efficient and innovative ways.[32] In order to facilitate the usage of complex notification and determination procedure, a World Bank study

[29] Ibid. Paragraph 2(a) (iii).

[30] Ibid. Paragraph 2(a) (1).

[31] Rohit Malpani and Mohga Kamal-Yanni, 'Patent versus Patients: Five Years after the Doha Declaration', Oxfam Briefing Paper (95) at http://www.oxfam.org/en/policy/briefingpapers/bp95_patentsvspatients_061114.

[32] Frederick M. Abbott and Jerome H. Reichman, 'The Doha Round Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions' (2007) 10(4) *Journal of International Economic Law* 921-987, 941.

in 2005 developed some model forms which Rwanda had used in 2007 to notify the WTO about its intention of using *Waiver Decision 2003*.[33]

The proposed Article 31*bis* and the *Waiver Decision 2003* would also regulate the conditions for issuing a compulsory licence for exporting Member States.[34] The authorised manufacturer from the exporting country can only manufacture and export the required quantities which the importing country has notified earlier.[35] On the insistence of developed countries, the so called safeguards against diversion are also enumerated in this regard which requires that the product should be clearly identified as having being produced under this system. This may involve special packaging, labelling, special shaping or colouring provided that the distinctions are feasible and do not significantly affect price.[36] Further conditions are put on the licensees to post destination and identification information on a website.[37]

Non-governmental organisations, international humanitarian organisations and academics have criticised the bureaucratic approach of the *Waiver Decision 2003* and the Article 31*bis*.[38] A 2006 report of *Médecins Sans Frontières (MSF)* notes:

> Prolonged prior negotiations severely limit the ability to use the August 30th Decision and act as a disincentive to manufacturers to participate in the process … Anti-diversion measures that generic companies must comply with are onerous and are further disincentives to their participation in the process.[39]

Highlighting the need for a viable and robust supply of pharmaceutical drugs, the report also considered the challenging task of manufacturing and supplying under compulsory licensing arrangement. In this regard, the MSF report complains that 'the Decision flies in the face of the practical reality of managing a health programme, where flexibility and rapidity of response to

[33] Frederick M. Abbott and Rupolph van Puymbroeck, 'Compulsory Licensing for Public Health, A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision, World Bank Working Paper No. 61 (2005).

[34] Paragraph 2(b) (i), *WTO General Council Decision of 6 December 2005 Amendment of the TRIPS Agreement*, WT/L/641, (8 Dec. 2005) (Protocol Amending the TRIPS Agreement' with Annex setting out Article 31bis) at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

[35] Ibid. Paragraph 2(b) (i).

[36] Ibid. Paragraph 2(b) (ii).

[37] Ibid. Paragraph 2(b) (iii).

[38] Médecins Sans Frontières, *Doha Derailed, A Progress Report on TRIPS and Access to Medicines* (Switzerland: MSF Campaign for Access to Essential Medicines, 27 August 2003) and Médecins Sans Frontières, *Neither Expeditious, Nor A Solution: The WTO August 30th Decision Is Unworkable: An illustration through Canada's Jean Chrétien Pledge to Africa* (Prepared for the XVI International AIDS Conference, Toronto August 2006), and Oxfam International, *Patents versus Patients, Five years after the Doha Declaration*, Oxfam Briefing Paper 95, November 2006.

[39] Médecins Sans Frontières (MSF), *Neither Expeditious, Nor A Solution: The WTO August 30th Decision Is Unworkable: An illustration through Canada's Jean Chrétien Pledge to Africa*, Prepared for the XVI International AIDS Conference, Toronto, August 2006, 3

ever-changing circumstances are vital'.[40] Some commentators have suggested that procurements strategies can incentivise the potential supplier and such policies can be used to overcome the problem of limited demand.[41]

E. Remuneration and Non-Authorised Importation

Article 31*bis* provides that adequate remuneration need only be paid in the country of export by taking into account the economic circumstances of the importing country.[42] The system requires the importing countries to take reasonable and proportionate measures to prevent diversion or re-exportation of medicines supplied under this arrangement.[43] The proposed Article 31*bis* obligates Member States to enable patent holders to protect themselves against unauthorised importation of pharmaceutical products manufactured under the system, but no additional legislative or administrative measures are required in this regard.[44]

F. Regional Arrangements

As the group of least developing countries from Africa was quite instrumental behind the development and adoption of the *Doha Declaration 2001* because of limited drugs manufacturing capacity within the region, the final solution addresses the need of such countries in a somewhat specialised and preferential way. The proposed Article 31*bis* contains a special provision for Member States that belong to regional trade agreements of which at least half the members are currently least developing countries.[45] For such a regional group, a relaxation is designed with regard to re-exportation to a member country once the product is manufactured and exported to one country under the compulsory licence. However, importing countries have not been discharged from the obligation of issuing separate compulsory licences where otherwise applicable.[46]

[40] Ibid. 4.

[41] Frederick M. Abbott and Jerome H. Reichman, 'The Doha Round Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions' (2007) 10(4) *Journal of International Economic Law* 921-987, 943.

[42] Paragraph 2, *WTO General Council Decision of 6 December 2005 Amendment of the TRIPS Agreement*, WT/L/641, (8 Dec. 2005) (Protocol Amending the TRIPS Agreement' with Annex setting out Article 31bis) at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

[43] Ibid. Paragraph 3.

[44] Ibid. Paragraph 4.

[45] Ibid. Paragraph 3.

[46] Ibid.

G. Implementation and Ratification

The *Waiver Decision 2003* was adopted after much deliberation and difficult negotiations and it was hoped that it would open a window of opportunities for least developing countries to boost their public health coverage programs. With the finalisation of the Protocol of Amendment in the form of Article 31*bis*, commentators were keen to look at the practical aspects of the new system as there were a number of concerns regarding the cumbersome nature of the proposed solution. To date, thirty-one countries including *European Communities* have notified their acceptance of the proposed amendment of the *TRIPS Agreement 1994*.[47]

However, the export scheme was not used until July 2007 when one least developing country, Rwanda, notified its intention to benefit from the scheme set out initially in the *Waiver Decision 2003*.[48]

The proposed Article 31*bis* would be rendered permanent in the form of an amendment to the *TRIPS Agreement 1994* once it is ratified by two-thirds of WTO members. By the December 2007 deadline, only 13 of 151 WTO countries had ratified it. The WTO pushed back the ratification deadline to December 2009 and in the meanwhile, the 2003 waiver remains in effect. With thirty-one countries accepting the proposed amendment in September 2010, it is anticipated that the Article 31*bis* would not be included into the *TRIPS Agreement 1994* in the wake of growing criticism and opposition of civil society organisation, and the situation may continue to be governed under the *Waiver Decision 2003*.[49] Moreover, there is some confusion about the status of the acceptance notification of the European Communities and individual community members have yet to notify their intentions.[50]

[47] These countries include United States (17 December 2005), Switzerland (13 September 2006), El Salvador (19 September 2006), Rep. of Korea (24 January 2007), Norway (5 February 2007), India (26 March 2007), Philippines (30 March 2007), Israel (10 August 2007), Japan (31 August 2007), Australia (12 September 2007), Singapore (28 September 2007), Hong Kong, China (27, November 2007), China (28 November 2007), European Communities (30 November 2007), Mauritius (16 April 2008), Egypt (18 April 2008), Mexico (23 May 2008), Jordan (6 August 2008)
Brazil (13 November 2008) Morocco (2 December 2008) Albania (28 January 2009) Macau, China (16 June 2009) Canada (16 June 2009) Bahrain (4 August 2009) Colombia (7 August 2009) Zambia (10 August 2009) Nicaragua (25 January 2010) Pakistan (8 February 2010) Former Yugoslav Republic of Macedonia (16 March 2010) Uganda (12 July 2010); and Mongolia (17 September 2010). See: World Trade Organization, Members Accepting Amendment of the TRIPS Agreement (updated 17September 2010) at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

[48] World Trade Organization, *Members Accepting Amendment of the TRIPS Agreement* (17 December 2010) at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

[49] Ibid. 984.

[50] Matthew Kennedy, When Will the Protocol Amending the TRIPS Agreement Enter into Force? (2010) 13(2) *Journal of International Economic Law* 459-473.

Most of the non-governmental organisations, humanitarian agencies and independent experts consider the system is defective in its design and modalities and it is extremely difficult for potential Member States to invoke it to meet their public health needs.[51] They maintain that conditions associated with the issuance of licences, notification requirements, the so-called safeguard clause and anti-diversion measures have unnecessarily over-burdened the system and it is very hard for least developing countries to overcome these barriers. James Love of the Consumer Project on Technology wrote about the *Waiver Decision 2003*: 'The new agreement has very modest benefits, and it has very substantial costs, risks and uncertainties.'[52]

This view is further augmented by the European Generic Medicine Association (EGA) declaring that WTO compulsory licensing system is unworkable and will not improve access to medicine. Mr Greg Perry, Director General of the EGA expressed his views recently at the WTO Public Forum 2008 and said: 'The WTO's 2003 August 30 Decision concerning compulsory licenses is complicated, unworkable and unable to deliver any significant improvement in access to medicines.'[53]

However, Frederick Abbott and Jerome Reichman construe the terms of the new system in a positive way suggesting that a better trade-off deal was practically not possible given the political and structural environment of trade negotiations at that time. They consider that most of the procedural requirements set out in the new system can be intelligently managed within national laws and willing Member States can overcome potential problems through pooled procurement strategies and innovative decision-making.[54]

However, in the light of theoretical analysis and the two cases (Rwanda and India), it is hard to construe the *Waiver Decision 2003* as a positive measure which can solve the problem of access to medicine. The decision is cumbersome and rigid and beyond its textual constraints, it also restricts the economic incentive which is essential to maintaining a manufacturing base.

[51] MSF Access to Medicines Campaign, *Doha Derailed, A Progress Report on TRIPS and Access to Medicines*, 27 August 2003 and *Neither Expeditious, Nor A Solution: The WTO August 30th Decision Is Unworkable: An illustration through Canada's Jean Chrétien Pledge to Africa*, Prepared for the XVI International AIDS Conference, Toronto, August 2006, and Oxfam International, Patents versus Patients, Five years after the Doha Declaration, Oxfam Briefing Paper 95, November 2006.

[52] James Love, 'CPTech Statement on WTO Deal on Exports of Medicines', August 30, 2003 at http://www.cptech.org/ip/wto/p6/cptech08302003.html.

[53] European Generic Medicine Association, 'WTO Compulsory Licenses System is Unworkable and Will Not Improve Access to Medicines' (Press Release 25 September 2008, Brussels at http://www.egagenerics.com/pr-2008-09-25.htm

[54] Frederick M. Abbott and Jerome H. Reichman, 'The Doha Round Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions' (2007) 10(4) *Journal of International Economic Law* 921-987, 941.

IV. Indian Compulsory Licensing Regime

After the series of sporadic amendments, India finally brought its patent law into conformance with the *TRIPS Agreement 1994* through the *Patents (Amendment) Act 2005 (India)*. It is important to see that India has incorporated the spirit of the *Waiver Decision 2003* in its domestic law to facilitate the smooth flow of generics export to other countries. The *Waiver Decision 2003* is merely an international instrument and its real potential will be demonstrated once put into operation under domestic laws and regulations. Through the *Patents (Amendment) Act 2005 (India)*, India has supposedly provided some robust and strong compulsory licensing avenues which yet need to be tested practically to judge its effectiveness.

The principal provisions dealing with compulsory licensing consist of Section 84, Section 92 and Section 92A of the *Patents Act 1970 (India)*. In addition to this, Section 11A also provides a mechanism for automatic compulsory licensing in certain cases. Here, I am focusing on the compulsory licensing provision relevant to pharmaceutical exports.

A. Section 92A: Doha Style Compulsory Licence

The *Patents (Amendment) Act 2005 (India)* introduces a third compulsory licensing avenue which reflects the WTO *Waiver Decision 2003* in domestic law. Section 92A provides for compulsory licences to enable exports of pharmaceutical products to those countries with no manufacturing capacity of their own. It states that:

> Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India. The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.[55]

This Section also defines the term 'pharmaceutical product' in line with the language of the *Waiver Decision 2003* and the proposed Article 31*bis* and includes 'any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their

[55] Section 92A(1) and (2) of the *Patents Act 1970 (India)*.

manufacture and diagnostic kits required for their use.'[56] An application for the grant of a compulsory licence under this Section can be filed at any time after a patent has been issued.[57]

Section 92A provides a relatively flexible and fast track Doha style licensing mechanism in view of the *Waiver Decision 2003* and the adoption of subsequent national laws in many Member States such as Canada, China, Norway and the European Union. It necessarily reflects the spirit of the *Waiver Decision 2003* and employs a less restrictive language and procedural requirements to issue a compulsory licence. For instance, Indian law does not explicitly require as a pre-condition that an importing country should have issued a licence before Indian law comes into action, and it merely puts the condition of a notification or otherwise to allow exportation of patented medicines. This provision was first introduced through the *Patents Ordinance 2004 (India)* and at that time it required that the exporter obtain a compulsory licence from the importing country as well.[58] However, this requirement was later dropped to accommodate situations where no such patent exists in the importing country and a notification would suffice in such cases.

The Section is completely silent about the requirements of specifying the amount of pharmaceutical products that will be manufactured under compulsory licence which is an important procedural aspect of the *Waiver Decision 2003*. Likewise, no requirements are mentioned with regard to separate packaging, colouring or shape. It is important to note that no such guidelines are currently under consideration when the Indian Patent Office is finalising its *Manual of Patent Practice and Procedure*.[59] This particular Section was scrutinised recently when the Indian generic manufacturer Natco applied for a compulsory licence for Roche's patented medicine, erlotinib, for export to Nepal.

B. Section 11A: Automatic Compulsory Licences

India was among those developing countries which opted to enjoy the full transition period allowed under the *TRIPS Agreement 1994*. Thus until 2005, India was not granting product patents for pharmaceutical and agro-chemical products and, in lieu, it had established a mailbox mechanism to determine priority matters in the post-2000 scenario. By virtue of this mailbox facility, applications would be judged for 'novelty' on the basis of the filing date and

[56] Ibid. Explanation.

[57] Ibid. No post grant waiting period is maintained under this Section unlike Section 84 of the Act.

[58] Shamnad Basheer, 'Indian Tryst with TRIPS: The Patents 9Amendment) Act 2005' (2005) 1(1) *The Indian Journal of Law and Technology* 15-46, 28.

[59] Intellectual Property India, Draft Manual of Patent Practice and Procedure at http://www.patentoffice.nic.in/ipr/patent/DraftPatent_Manual_2008.pdf

not with reference to 2005, the year in which product patents were first incorporated into the patent regime. The *Patents (Amendment) Act 2005 (India)* provides that where a patent is granted to any of those mailbox applications, an automatic compulsory licence would issue to those generic companies that made a 'significant investment' and were 'producing and marketing' a drug covered by the mailbox application prior to 2005. Such licence is subject to the payment of a reasonable royalty.[60]

There has been much discussion about the Indian compulsory licensing regime and a range of positions can be identified in this regard. First, the Pharmaceutical Research and Manufacturer of America (PhRMA) in its 2008 submission to USTRA termed the Indian compulsory licensing provisions as one of the most damaging provisions of the Indian Patent Law.[61] Second, some commentators consider that the Indian export oriented compulsory licensing regime is the broadest in scope when compared with other jurisdictions and thus 'widespread use of the Section 92A avenue for compulsory licensing to export patented medicines appears likely'.[62]

However, I would argue here that the Indian compulsory licensing provisions under Section 92A should be understood and analysed both in a legal and factual context. A study undertaken for WHO shows that very few Indian pharmaceutical companies think that the Indian patent law provides an economically lucrative option for them to retain their export sales. Of the 103 firms, only 25 firms thought it was an economically lucrative option, whereas 78 firms did not think so. It is important to note that out of 25 firms which responded positively, only 6 firms have a strong technological base to meet export market demand on a sustainable basis.[63]

V. Tarceva and Sutent Compulsory Licences

The Indian compulsory regime has been tested by two separate compulsory licence applications for anti-cancer medicines involving erlotinib and sutent.

[60] Section 11A Proviso of *Patents Act 1970 (India)*.

[61] Pharmaceutical Research and Manufacturer of America, 'Special 301 Submission 2008', February 11, 2008, 68, at http://www.ustr.gov/assets/Trade_Sectors/Intellectual_Property/Special_301_Public_Submissions_2008/asset_upload_file109_14495.pdf

[62] Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 68 *University of Pittsburgh Law Review* 491-641, 604 at http://lawreview.law.pitt.edu/issues/68/68.3/Mueller.pdf

[63] Padmashree Hehi Sampath, 'Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry' Institute of New Technologies, United Nations University at http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf

A. Erlotinib hydrochloride

Erlotinib which is marketed by Genentech, OSI Pharmaceuticals and Roche in different parts of the world under the brand name Tarceva, is prescribed for the treatment of non-small cell lung cancer and pancreatic cancer. It is basically a small molecule human epidemic growth factor type 1/epidermal growth factor receptor inhibitor which was approved in November 2004 by the U.S. Food and Drug Administration (FDA).[64] The drug is primarily developed by OSI Pharmaceuticals and later business and marketing partnerships were developed with Genentech and Roche. Now OSI Pharmaceuticals and Genentech are marketing the Tarceva brand in the United Sates, and elsewhere it is marketed by Roche. After its marketing approval in 2004, Tarceva did quite well in the global oncology market by generating substantial revenue for marketing companies.

In its Business Report 2007, the Roche Group declared Tarceva among its top selling pharmaceutical products with sales of 1,062 million Swiss Francs. The Report indicates a 31% annual increase in sales.[65] Genentech markets this drug jointly with OSI Pharmaceutical and in 2007 it reported US $417 million sales with a steady annual growth since 2006.[66] For OSI Pharmaceuticals, Tarceva stands as the single most important drugs for business and revenue purposes. In 2007, it reported revenues of $340 million (up 41% on the prior year) and it was observed:

> The business continues to be anchored around our flagship anti-cancer therapy Tarceva® which, just three years after the November 2004 approval in non-small cell lung cancer (NSCLC), exited the year with fourth quarter global sales of $250 million – an annualized run-rate of $1 billion, the recognized industry-wide metric of a blockbuster.[67]

B. Tarceva Patents

OSI Pharmaceuticals and Roche secured the patents of erlotinib (the active pharmaceutical ingredient of Tarceva) in the United States, Europe, Japan, and number of other countries. Indeed, Roche claimed in India that patents related to Tarceva had already been filed in more

[64] U.S. Food and Drug Administration Consumer Information at http://www.fda.gov/cder/consumerinfo/druginfo/Tarceva.HTM.

[65] Roche, *Annual Report 2007: We Innovate Healthcare* (Switzerland: 2007), 19 at http://www.roche.com/gb07e.pdf.

[66] Genentech, *Annual Report 2007: In Business for Life* (California: 2007) 23, at http://www.gene.com/gene/about/ir/historical/annual-reports/2007/2007annualreport.pdf

[67] OSI Pharmaceuticals, Annual *Report 2007* (New York: 2007) 1, at http://media.corporate-ir.net/media_files/irol/70/70584/2007_OSIP_Annual_Report.pdf

than 80 countries and in almost 50 countries it was granted.[68] In the United States, the Orange Book data shows two patents related to Tarceva which would respectively expire on March 30, 2015 (Patent No. 5747498) and November 9, 2020 (Patent No 6900221).[69] In addition to this, OSI Pharmaceuticals was granted patent term extension certificates which extend the United States patent to November 2018 and a corresponding patent in Europe to March 2020.[70] Further patenting activity is expected around erlotinib given its emerging importance and ongoing research regarding the possibility of future use of the same molecule for pipeline products. OSI Pharmaceuticals states in this regard:

> We are also currently pursuing U.S. and international patents for new inventions concerning various other formulations of erlotinib and related intermediate chemicals and processes in an effort to enhance our intellectual property rights in this compound. We have obtained a patent covering a key polymorphic form of Tarceva in the United States, which expires in 2020. We are also currently seeking patent protection for additional methods of use for Tarceva, including the use of Tarceva in combination with other compounds.[71]

In India, Pfizer Inc. USA and OSI Pharmaceuticals jointly filed an erlotinib patent application on 30th March 1995. The invention claimed in the patent application was related to 'Quinazoline Derivatives Compounds and Composition thereof' with initially 27 claims.[72] It is worthwhile mentioning that the corresponding US patents showed a broader claim strategy where 79 claims were made under United States Patent No. 6,900,221.[73] The other US patent related to erlotinib contains 32 claims.[74] However, realising the very broad scope of claims made in Patent No. 5,747,498 which may become ultimately susceptible to challenge under

[68] *F. Hoffmann-La Roche Ltd v Cipla* (I.A 642/2008 IN CS (OS) 89/2008) dated March 19 2008, paragraph 65, Full text is available at: http://courtnic.nic.in/dhcorder/dhcqrydisp_j.asp?pn=1031&yr=2008.

[69] Approved Drug Products with Therapeutic Equivalence Evaluations in Electronic Orange Book at http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021743&Product_No=001&table1=OB_Rx

[70] OSI Pharmaceuticals Annual Report 2007, 12, at http://media.corporate-ir.net/media_files/irol/70/70584/2007_OSIP_Annual_Report.pdf

[71] Ibid.

[72] Decision of Assistant Controller of Patents and Designs in the matter of patent application No. 537/Del/1996 at https://210.210.88.164/patentdecisionsearch/display_uploaded.asp?application_number=537-DEL-1996-154

[73] Norris, Timothy et al (2005), 'Stable polymorph on N-(3-ethynylphenyl)-6, 7-bis (2methoxyethoxy)-4-quinazolinamine hydrochloride, methods of production, and pharmaceutical uses thereof', US Patent No: 6,900,221 at http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=6,900,221.PN.&OS=PN/6,900,221&RS=PN/6,900,221

[74] Schnur, Rodney Caughren (1998), 'Alkynyl and azido-substituted 4-anilinoquinazolines' United States Patent No: 5,747,498 at http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=5747498.PN.&OS=PN/5747498&RS=PN/5747498

Paragraph IV procedure of the *Drug Price Competition and Patent Term Restoration Act* (Hatch-Waxman Act), OSI Pharmaceuticals filed an application in February 2008 to the *United States Patent and Trademark Office* to correct certain claims by deleting surplus compounds from the claims.[75]

The Indian Patent Office had already raised these objections with regard to the erlotinib patent application and on 22 January, 2006, eleven preliminary objections were raised in the First Examination Report of the Indian Patent Office including the lack of novelty and the inventive step.[76] These objections were later removed and finally the applicants managed to secure a patent on the following two claims:

1. A novel [6,7-bis(2-methoxyethoxy)quinazolin-4-yl]-(3-ethynylphenyl) amine hydrochloride compound of the formula A, and
2. A process for preparing the compound as claimed in claim 1.[77]

C. Pre-Grant Opposition by Natco Pharma

After the case was put for the final grant of patent, Natco Pharma Ltd., a local generic manufacturer, filed an opposition to the grant of patent on 10th April 2007. This application was made under Section 25(1) of the *Patents Act 1970 (India)* which deals with pre-grant opposition proceedings. The grounds on which pre-grant opposition may be based include virtually all patentability criteria including anticipation, lack of inventive step and non-invention.[78] In its opposition petition, Natco Pharma mainly raised concerns about whether the application was non-obvious, and whether there had been sufficient disclosure of the invention in the specifications.[79]

In view of these objections, the Indian Patent Office examined the question of the novelty and inventive step again in the light of prior art citation EP 0566226, published on 20.10.93 and EP 0520722 published on 30.12.92. In the end, it decided that none of the citations were specific for the claims made under the patent application. The opponent maintained that the

[75] OSI Pharmaceuticals Annual Report 2007, 12, at http://media.corporate-ir.net/media_files/irol/70/70584/2007_OSIP_Annual_Report.pdf

[76] Decision of Assistant Controller of Patents & Designs in the matter of patent application No. 537/Del/1996, 11. Full text available at https://210.210.88.164/patentdecisionsearch/display_uploaded.asp?application_number=537-DEL-1996-154.

[77] Ibid. 13.

[78] Section 25 (1) a-k of the *Patents Act 1970 (India).*

[79] Decision of Assistant Controller of Patents & Designs in the matter of patent application No. 537/Del/1996, 14. Full text available at https://210.210.88.164/patentdecisionsearch/display_uploaded.asp?application_number=537-DEL-1996-154.

claimed invention was an obvious derivative derived from 4-Anilinoquinazoline nucleus and 'the combination of simple functional groups like alkoxy, alkyl, alkynyl, halo to already known basic nucleus or compound is obvious to a person of ordinary skill in the art'.[80] Applicants also survived the attack on their claims on the basis of Section 3(d) of the *Patents Act 1970 (India)* by showing the data regarding survival rate increase by the use of drug. The Patent Office decided in favour of applicants and the patent was granted accordingly against two claims agreed during the proceedings.

During the hearings, the parties could not agree on the nature of opposition proceedings with Natco considering it as a pre-grant opposition under Section 25(1) and OSI Pharmaceuticals and others as a post-grant opposition under Section 25(2). This confusion basically arose because of an earlier decision by the Patent Office on its own objections and the subsequent order for the grant of patent which was delayed due to internal processes. This distinction is important from the point of view of the possibility of filing a post-grant opposition, though Natco could not succeed in its pre-grant opposition. On this point, the Patent Office decided that the proceeding was a pre-grant opposition.[81] The success in pre-grant opposition was an important victory for OSI Pharmaceuticals and other parties and its Annual Report 2007 states: 'A patent corresponding to the U.S. composition of matter patent for Tarceva was granted in February 2007 in India and we, along with our collaborator Roche, successfully opposed a pre-grant opposition by Natco Pharma, Ltd. of Mumbai, India in July 2007.'[82]

D. Sunitinib Malate

Sunitinib Malate is prescribed for the treatment of renal cell carcinoma, a type of kidney cancer. It is manufactured and marketed by Pfizer under the brand name sutent and also used for the treatment of gastrointestinal stromal tumour (GIST). GIST is a cancer of the stomach and bowels which is caused by the uncontrolled growth of cells in the wall of the stomach or bowel. Sutent was the first medicine approved by the U.S. Food and Drug Administration (FDA) simultaneously for two indications. While approving the drug in January 2006, Steven Galson, Director of FDA's Center for Drug Evaluation and Research, observed: 'Today's approval is a major step forward in making breakthrough treatments available for patients with rare and difficult to treat forms of cancer.'[83]

[80] Ibid. 19.

[81] Ibid. 26.

[82] OSI Pharmaceuticals Annual Report 2007, 13, at http://media.corporate-ir.net/media_files/irol/70/70584/2007_OSIP_Annual_Report.pdf

[83] U.S Food and Drug Administration, '*FDA Approves New Treatment for Gastrointestinal and Kidney Cancer*', January 26, 2006, P06-11 at http://www.fda.gov/bbs/topics/news/2006/NEW01302.html

In Pfizer's product portfolio, sutent is still categorised as one of the new medicines which is performing very well with an increase of 166% in sales revenue during 2006.[84] Sutent's sales revenue increased to US$581 million in 2006 and that was mainly because of its widespread and speedy marketing approval in Europe and many Asian countries.

E. Sutent Patents

In the United States, three patents were granted for sunitinib malate which would expire on February 15, 2021 (Patent No. 6573293 and Patent No. 7125905) and December 22, 2020 (Patent No. 7211600). In addition to this, a New Chemical Entity (NCE) exclusivity protection is also applicable until January 26, 2011.[85] A PCT application (Application No. PCT/US1999/012069) was also filed in 1999 and the patents were granted in several designated countries between 2001 and 2005.[86] The parallel Indian patent application was filed on August 9, 2002 under the title of Pyrrole Substituted 2-Indolinone Protein Kinase Inhibitors and a patent was granted on August 31, 2007.[87] This patent (Patent No. 209251) was granted jointly to Sugen Inc. and Pharmacia & Upjohn Company. Sugen was a small California based biotechnology company which was acquired by Pharmacia & Upjohn Company in the late 1990s and subsequently Pharmacia & Upjohn Company was acquired by Pfizer in 2003. However, Pfizer kept using these distinct business identities as a business strategy.[88]

Patent protection is central in Pfizer's business strategy and one of its foremost business strategies is to refocus and optimise its patent protected portfolio.[89] In its Annual Review of 2007, Pfizer declared: 'We are refocusing and optimizing our patent-protected portfolio to speed up the flow of new products, invest more in areas of strength, and deliver greater value to customers and patients.'[90] In this context, an attempt to secure compulsory licences for these two drugs was really seen as an offensive move by the patent owners and both applications were fiercely contested in the patent office.

[84] Pfizer, *Annual Review 2007* (New York: 2007) 7

http://media.pfizer.com/files/annualreport/2007/annual/review2007.pdf

[85] Approved Drug Products with Therapeutic Equivalence Evaluations in Electronic Orange Book at http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021938&Product_No=001&table1=OB_Rx

[86] Tang, Peng Cho et al (Filed in 1999), 'Pyrrole Substituted 2-Indolinone Protein Kinase Inhibitors', PCT Application No: PCT/US1999/012069 at http://www.wipo.int/pctdb/en/wo.jsp?WO=1999061422&IA=US1999012069&DISPLAY=STATUS

[87] Government of India, Controller General of Patents Designs and Trademarks at https://124.124.220.66/patentgrantedsearch/(S(k3gh1m55vis3y1rkuwtxcx55))/GrantedSearch.aspx.

[88] Pfizer *Annual Review* 2007, 14, http://media.pfizer.com/files/annualreport/2007/annual/review2007.pdf.

[89] Ibid. 4.

[90] Ibid. 12.

F. Natco's Compulsory Licence Application

Notwithstanding the unsuccessful attempt to block the erlotinib patent through a pre-grant opposition procedure, Natco Pharma Ltd. applied for compulsory licences under Section 92A of the *Patents Act 1970 (India)*. As mentioned earlier in this chapter, Section 92A provides the avenue for the grant of a Doha style compulsory licence solely for export purpose. In early January 2008, Latha Jishnu of the *Business Standard* reported that:

> [T]he first application for a compulsory licence filed in India, has put a key provision of the Indian Patents (Amendment) Act, 2005 under the scanner. The application has been filed by Natco Pharma of Hyderabad for Roche's erlotinib (brand name Tarceva), which is used in the treatment of lung cancer.[91]

In its application to the Patent Office for the grant of a compulsory licence under Section 92A, Natco asked for permission to manufacture 30,000 tablets of Tarceva for export to Nepal against a fixed royalty of 5%. Later, it was also reported that Natco applied for a compulsory licence of Sunitinib against the same terms and conditions.[92]

G. Nepal: Public Health Profile and Access to Medicines

Nepal is a least developing country in South Asia having boundaries with China in the north and India in the south. With a population of 27,641,000 its gross national income per capita is US$1,010.[93] The share of annual health expenditure as a percentage of the national budget was 5.1% in 2001-03. Nepal's rank in terms of the UNDP Human Development Index (HDI) is 142 among 177 countries.[94]

There have been a number of estimates of cancer incidence in Nepal. Some estimates show that the incidence of cancer is approximately 120 per l00,000 head of population, and it is assumed that there are 35,000 to 40,000 cancer sufferers in the country.[95] The incidence of cancer is thought to be rising every year. The hospital based statistics showed that there were 23% cases with malignancies in 1993 compared to 19% in 1989. The five most common malignant

[91] Latha Jishnu, 'Cancer drug puts licence, patent rules to test', *Business Standard*, January 16 2008, at http://in.rediff.com/money/2008/jan/16drug.htm

[92] Tatum Anderson, 'India Considers Compulsory Licences For Exportation of Drugs', *Intellectual Property Watch*, 20 February 2008, at http://www.ip-watch.org/weblog/index.php?p=933

[93] World Health Organization Country Statistics at http://www.who.int/countries/npl/en/

[94] World Health Organization, '2007/2008 Human Development Index rankings' at http://hdr.undp.org/en/statistics/.

[95] Sunil Kumar Joshi, 'Occupational Cancer in Nepal – An Update' (2003) 1(2) *Kathmandu University Medical Journal* 144-151, 144 at http://member.wnso.org/drsunilkj/Occupationalcancer.pdf

diseases in Nepal are bronchial cancer, breast cancer, cervical and ovarian cancer, stomach and colorectal cancer and leukaemia.[96] The Nepal pharmaceutical industry is largely dependent upon the Indian market and most of local manufacturers are importing their raw materials from India and China (see Table 4.2)

Table 1.2: Top 15 Suppliers to Nepal

Rank	Company	Origin	Value (in crore)	Market Share (%)
1	Nepal Pharma	Nepal	13.2	3.85
2	Lomus Pharma	Nepal	11.8	3.47
3	Aristo	Indian	11.4	3.31
4	Deurali Janata	Nepal	10.7	3.08
5	Knoll Pharma	MNC	9.6	2.78
6	Dabur	Indian	9.1	2.65
7	Lupin	Indian	8.7	2.50
8	National Health Care	Nepal	8.6	2.50
9	Hoechst	MNC	8.1	2.35
10	Alkem	Indian	7.8	2.27
11	Ranbaxy	Indian	7.4	2.14
12	Cadila Pharma	Indian	6.3	1.84
13	Cadila Health Care	Indian	6.3	1.83
14	E Merck	MNC	6.0	1.75
15	Novartis	MNC	5.6	1.64

Source: Dr R. K. Srivastava[97]

Nepal joined the WTO on April 23, 2004[98] and it is regarded as at least a developing country for implementation and enforcement of various treaty related obligations including the *TRIPS Agreement 1994*. Historically, Nepal had domestic intellectual property laws but it had to amend those laws in the light of obligations of the *TRIPS Agreement 1994* by January 1, 2006.[99] This is

[96] Ibid.

[97] Dr R. K. Srivastava, 'Nepal-New Emerging Pharma Market' (undated) http://www.p-m-c.com/PMC%20WEB%20_articles/Nepal%20New%20Emerging%20Pharma%20Market.doc

[98] World Trade Organization, 'Member Information: Nepal and WTO' (accessed on September 13, 2010) at http://www.wto.org/english/thewto_e/countries_e/nepal_e.htm

[99] World Trade Organization, 'WTO Ministerial Conference Approves Nepal's Membership' (accessed on September 13, 2010) at http://www.wto.org/english/news_e/pres03_e/pr356_e.htm

of course subject to the *Doha Declaration*'s extended deadline for least developing countries to apply provisions on pharmaceutical patents until 1 January 2016.[100]

As a least developing country, Nepal has as yet no obligation to protect pharmaceutical products under patent law. According to the *Patent, Design and Trademark Act 1965 (Nepal)*, a patent is defined as 'any useful invention relating to a new method or process of manufacture, operation or publicity of any material or a combination of materials, or that made on the basis of a new theory or formula'.[101]A patent is valid only for 15 years after registration.[102] There has been a little patenting activity in Nepal and only 49 Patents were registered until 2002.[103]

Natco's compulsory licensing applications have generated substantial debate in India and elsewhere but surprisingly there is complete silence from Nepal. Though these compulsory licenses were intended to be used for export to Nepal but we can see virtually no debate in Nepal about this issue. With the status of a least developing country, Nepal has no obligation to respond to this situation with a domestic compulsory license and its mere notification should suffice in the given circumstances. In fact, there is no compulsory licensing related provision in the *Patent, Design and Trademark Act 1965* (Nepal). However, for a successful outcome of Natco's application in India, at least two factors are important in Nepal. First, Nepal should determine and establish its public health need with regard to products which Natco is attempting to manufacture under compulsory license. Second, Nepal should notify the WTO about its intention to invoke the *Waiver Decision 2003*, much like Rwanda

Natco's attempt looks half-hearted and apparently it rushed to the patent office without adequate preparation. These points were justifiably highlighted by the patentees before the patent office and played a decisive role in the final outcome. The matter is further discussed in subsequent sections. Pfizer's presence in Nepal and its pricing policy there is another aspect of this debate which is not discussed by the commentators. Aiming clearly to counter Natco's compulsory licensing application, Pfizer announced the launch of a free sutent access program in Nepal.[104] The decision was first revealed in April 2008, much later than the filing of the compulsory licensing applications in India.

[100] World Trade Organization, 'The Doha Declaration Explained' (accessed on September 13, 2010) at http://www.wto.int/english/tratop_e/dda_e/dohaexplained_e.htm

[101] Section 2(a) of the Patent, Design and Trade Mark Act, 1965 at http://www.vakilno1.com/saarclaw/nepal/patentandtrademarkact/chapter1.htm

[102] Section 8 (1) of the Patent, Design and Trade Mark Act, 1965 at http://www.vakilno1.com/saarclaw/nepal/patentandtrademarkact/chapter1.htm.

[103] Sirjana Sharma, 'Intellectual Property Law' on *Nepalese Lawyers in the US* (January 11, 2008) at http://anlus.wordpress.com/2008/01/11/article-intellectual-property-law/

[104] C.H. Unnikrishnan, 'Pfizer to launch free Sutent access programme in Nepal; *The Wall Street Journal*, April 3, 2008 at http://www.livemint.com/2008/04/03004838/Pfizer-to-launch-free-Sutent-a.html?d=1 (Note that 'The move may upset Indian generic drug maker Natco Pharma Ltd's efforts to secure a compulsory licence for exporting copy-cat versions of the drug'.)

H. Procedural Requirements

In contrast to the *Doha Declaration 2001* and the *Waiver Decision 2003*, Section 92A adopts a straightforward and relatively fast track mechanism to issue a compulsory licence for export purposes. This provision does not stipulate the requirement of issuance of two back-to-back compulsory licences in importing and exporting countries along with separate notification obligations. In fact, the provision is silent about the royalty payment and no formula is referred for its calculation. However, the Patent Controller is authorised under the relevant provision to determine the terms and conditions of such licence.

Despite the gaps in Section 92A, it is important to note that the whole scheme is designed to meet the obligations of the *Doha Declaration 2001* and any interpretation of this section should be construed against this background. In light of the *Doha Declaration 2001* and related provisions of Indian law, Natco's application can be analysed in the following way.

According to the *Doha Declaration 2001*, an importing country is obliged to notify the *Council for TRIPS* about the name and expected quantity of the drug which it intends to import under the scheme. The Declaration further requires that the member state must establish beforehand that it has virtually no, or a very limited, manufacturing capacity with regard to the drug which it wants to import and it should issue a compulsory licence if the product is patented in that importing country. In this case, Nepal is a least developing country and it does not need to establish its insufficient manufacturing capacity pursuant to the *Doha Declaration 2001.* Given that Nepal has no product patent regime, issuing a compulsory licence has no relevance. However, general notification of intent to the *Council for TRIPS* is required which Nepal has not made. In the very first Doha-style compulsory licensing case, Rwanda had notified its intention to use the mechanism of the *Doha Declaration 2001.*[105]

It is unclear how the Indian Patent Office will operate in the absence of such a notification to the *Council for TRIPS.* Nepal has only reportedly issued an import letter in favour of Natco. The contents of this letter which was issued from the Nepalese Ministry of Health are not yet known so its adequacy in terms of satisfying the procedural requirement of *Doha Declaration 2001* is yet to be established. This point was precisely raised by the patentees during a hearing before the Patent Office and an objection was raised as following:

> Counsel for patentees further argued that the "notice" by the Nepal government that Natco was relying upon was insufficient to amount to a formal notification of an intent to import drugs produced under a compulsory licence. He alleged that Natco, in its application for a compulsory licence, had merely submitted a letter from the Nepal government recommending that one consignment of erlotinib be approved for import

[105] *Rwanda- Notification under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/N/9/RWA/1 (19 July 2007) at http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm

> from India during the period 2006-2007. He argued that this was insufficient to demonstrate Nepal's intent to utilise the 30 August mechanism to import drugs produced under a compulsory licence. In contrast, he pointed to the formal notification provided to the WTO by Rwanda of its intent to utilise the paragraph 6 implementation.[106]

Setting aside the procedures of the *Doha Declaration 2001* for a moment, Natco can argue that Indian law does not prescribe the requirement of notification to the *Council for TRIPS* and any document establishing the intent of the importing country should be considered satisfactory.

Indeed, a bare reading of Section 92A supports this assertion as it states:

> Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, *by notification or otherwise*, allowed importation of the patented pharmaceutical products from India.[107] (emphasis added)

Once the importing member country fulfils the requirement, then the exporting country can issue a compulsory licence under its domestic law. In this case Natco has applied to the Patent Office after securing a letter from Nepal stating its intent, the name of the product, required quantities and a royalty offer. This licence is necessary in India given the existence of a valid patent by OSI Pharmaceuticals and Pfizer.

In the absence of any notification from Nepal, it is difficult to determine the prevalence of a public health problem and its nature. Paragraph 1 of the *Doha Declaration 2001* clearly spells out the intent by linking it with public health problems. It is not necessary for Nepal to show a national emergency before importing drugs from India under the Indian compulsory licence but such an action should definitely be related to a public health problem. The relevance of an anti-cancer drug contrary to an HIV/AIDS treatment may become a contentious point as we have already seen this line of argument the case of Thailand.[108]

[106] Chan Park, 'Natco's application for CL for Export – Hearing in the Delhi Patent Office' on *Commons-Law Blog* (March 20, 2008) at http://commonslaw.freeflux.net/blog/archive/2008/03/20/commons-law-natco-s-application-for-cl-for-export-hearing-in-the-delhi-patent-office.html

[107] Section 92A(1) and (2) of the *Patents Act 1970 (India)*.

[108] Jonathan Burton-MacLeod, 'Tipping point: Thai Compulsory Licences Redefine Essential Medicines Debate' in Thomas Pogge, Matthew Rimmer and Kim Rubenstein (eds), *Incentives For Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press: 2010) 77. Also see: Office of the United States Trade Representative, *2009 Special 301 Report* (April 30, 2009) 21 at http://www.ustr.gov/sites/default/files/Full%20Version%20of%20the%202009%20SPECIAL%20301%20REPORT.pdf

I. The Right to a Hearing

In response to Natco's application, Pfizer approached the Patent Office to contest the matter both on its merits and on procedural grounds. Indeed, the Patent Office itself identified some lacunas in Natco's application and those were communicated to the applicant. Natco responded to those points and maintained that patentees had no right to be heard in this case. On the questions of maintainability of this application and the patentees right to become a party, two hearings were held and finally the Patent Office resolved this matter to the extent of a hearing right in favour of patentees.

It is pertinent to note that Section 92A of the *Patents Act 1970 (India)* is silent on the question of a patent holder's right to a hearing and relevant rules along with draft *Manual of Patent Practice and Procedure* are equally unhelpful in this regard. Natco interprets it as a fast track compulsory licensing avenue unlike other provisions and asserts that a hearing right would unnecessarily delay the licence issuance process. Patent holders believe that their right to a hearing is inherent and based upon natural justice and several provisions of patent law. This question arose in discussion during the first two hearings when deliberations on the merit of the application were set aside for a while and parties argued their position on this preliminary hiccup. The parties raised several crucial points in their submissions.

To resolve this matter and decide about the stay petition of Natco, the Delhi Patent Office held a hearing on March 19, 2008. This hearing was attended by the parties and representatives of the Lawyers Collective, the HIV/AIDS Unit and the MSF Access Campaign. The latter two parties attended the proceedings as observers and the counsel of patentees raised objections about their presence asserting the proceedings as a private hearing. However, it was finally resolved that the observers could attend the proceedings with the objection of patentees placed on the record.[109]

In favour of their position, patentees relied both on statutory and common law grounds to establish the right to hearing before a compulsory licence was issued. The Patentee argued that under the notion of 'natural justice' and 'due process', a hearing opportunity was fundamental before any decision adverse to their right was considered. Further reliance was made on Section 80 of the *Patents Act 1970 (India)* and Rule 129 of the *Patents Rules 2003 (India)*. A joint reading of Section 80 and Rule 129 suggest that the Patent Controller is required to grant a patent applicant, or any party to a proceeding, a hearing before exercising any discretionary power adversely. Thus, it was argued, the patentees had a right to be heard before the grant of compulsory licence.[110] Pfizer also relied upon a number of Indian cases to establish its position

[109] Chan Park, 'Natco's application for CL for Export – Hearing in the Delhi Patent Office', Commons-Law Blog at http://commonslaw.freeflux.net/blog/archive/2008/03/20/commons-law-natco-s-application-for-cl-for-export-hearing-in-the-delhi-patent-office.html

[110] Ibid.

on the right to be heard and in this regard reliance was made *on* audi alterum partum.[111] The same principle was upheld in several other cases such as Union of India v. T.R. Verma[112], Basudeo Tiway v. Sido Kanhu Uni[113] and Udit Narayan Singh v. Additional Member Board of Revenue.[114]

In response to such assertions, the applicant (Natco) maintained that Section 92A was clear in its language and intention and such hearing was deliberately avoided at the time of amendments in the law. Section 92A was a clear response to the mandate of the *Doha Declaration 2001* and the legislature intentionally adopted a fast track and efficient mechanism to meet the public health challenges in importing countries. Thus, a clear distinction was made between the general compulsory licensing provisions (Sections 84-92) and this provision (Section 92A). Domestic compulsory licensing provisions clearly provide a hearing opportunity and Section 92A is deliberately silent on this point to expedite the procedure. Natco insisted that Section 92A could be construed in the light of the *Doha Declaration 2001* which prompted the need for rapid response in the case of a public health crisis. Natco maintained that:

> On analysis of the section 92 (A) of the Indian Patents Act, it is clear that law specifically excludes any interference or intervention or even participation by the patentee. Therefore, the question of contesting the grant of license does not arise. The entire mechanism is a departure from the usual procedure of grant of compulsory license and is aimed at giving effect to and fulfilling the objectives of said Doha Declaration which emphasizes on the rapid response to the urgent needs of the least developed countries or developing countries for immediate access to patented medicines.[115]

Natco also referred to the relevant Canadian legislation (Section 21.14) where no such right was incorporated in the law before the issuance of a compulsory licence.[116] In response to the patentees' position that certain matters could only be determined with the assistance of patentees, Natco relied on the joint publication of WHO/UNDP which could be used to work out adequate remuneration in such circumstances without the involvement of the patentees.[117]

[111] *Maneka Gandhi* v *Union of India* (1978) 1 SCC 248.

[112] Union of India v T.R. Verma *AIR 1957 SC 882.*

[113] Basudeo Tiway v Sido Kanhu Uni *(1998) 8 SCC 194.*

[114] Udit Narayan Singh v Additional Member Board of Revenue *AIR 1963 SC 786.*

[115] Delhi Patent Office, Government of India, No. POD/HK/2008-09012942 Dated July 4, 2008 at https://124.124.220.66/patentdecisionsearch/display_uploaded.asp?application_number=IN-PCT-2002-00785-DEL-167

[116] Ibid.

[117] In fact reference was made to: James Love, 'Remuneration Guidelines for a non voluntary use of a patent on medical technologies, UNDP-WHO Health Economic and Drugs TCM Series No. 18 (WHO/TCM/2005.1), (2005).

It further argued that the common law doctrine of natural justice could not be applied in an absolute manner and it had always been regulated under different situations and in view of the unambiguous language of Section 92A, general rules could not be attracted.

The Patent Office finally resolved the matter of the hearing controversy on July 4, 2008. In his decision, Hrdev Karar, Assistant Controller of Patents and Design, dismissed the interlocutory petition of Natco and allowed the patentees to become parties to proceedings before the Patent Office in the matter under Section 92A. The Patent Office decision is important in view of future applications of Section 92A and it would eventually pave a way towards elaborative and lengthy proceedings before the grant of a compulsory license.

The decision is mainly about the patentee's right to participate in proceedings held under Section 92A and several other points were also discussed by the Assistant Controller regarding the maintainability of Natco's application. For instance, it is noticed that Natco could not substantiate its application for the grant of a compulsory licence by producing a notification from the Government of Nepal. The letter which Natco had attached along with its original application was declared insufficient in the light of legislative requirement. Natco did not submit proof to suggest that there was a public health emergency in Nepal due to the lack of availability of the drug. The Assistant Patent Controller, therefore, stated in his order that one of the reasons for the 'hearing' was to ensure that the provisions of 92 (A) were not 'abused'.

The participation of patentees and their hearing right are recognised in the decision in purview of Section 92A and the applicant's submission on this point was turned down. Agreeing with the patentees' arguments on this point, the Assistant Controller of Patents and Design said:

> It may be observed that the requirements as mentioned in section 92A and rules made thereunder impliedly demands the presence of the patentee, therefore the doctrine "necessary implication or the maxim expression '*unius est exclusio alterius*' need not to be applied. The principle *audi alteration partem* would be more beneficial for proper administration of justice. Therefore, the patentee is required to be invited to the hearing in respect of proceedings of section 92(A).[118]

The hearing controversy is now resolved by this decision and the remaining matter is to be decided on its merits. This initial controversy raised important procedural questions which have the potential to stall a compulsory licence application for a considerable time. An unrestricted and full-fledged hearing right may hamper the development of a standard working procedure which can be later employed by other generic companies to apply for compulsory licences under Section 92A. This first case is highly important not only for Indian manufacturers but also for the rest of the developing world as the placement of a quick and efficient mechanism in India would help them activate their domestic regulations to important

[118] Ibid. 13.

cheaper drugs from generic resources. Obviously any unnecessary delay or cumbersome procedure should be considered against the legislative intent and procedural requirements under Section 92A.

J. Withdrawal of Application by Natco

After this decision, it was expected that the matter would shift to normal proceedings and the patent office would decide about the grant of compulsory licence after hearing both parties. Though the decision was disappointing for Natco it was expected that Natco would strongly push its case on the merits for the grant of a compulsory licence. However, in September 2008, Natco requested the Controller of Patents to withdraw its applications for compulsory licenses for export of the generic anti-cancer drugs sunitinib and erlotinib.[119]

Apparently it was an unexpected move although some commentators noted that it was anticipated after Patent Office's decisions on Natco's interlocutory petition. Shamnad Basheer observed that:

> [P]atent office was concerned that the Doha CL process ought not to be abused by generic manufacturers that wished to make a quick buck. Therefore, the best way to ensure this was to hear the other side as well ... Natco's decision to withdraw its application may have stemmed from a fear that it would lose on merits.[120]

The outcome is indeed disappointing for a variety of reasons. First, this case was a good chance for Indian generic companies to test the application of export oriented compulsory licences. Second, the decision of the Patent Office was unreasonable in that it had indeed determined the outcome of Natco's application beforehand. The decision expressed serious doubts about the maintainability of a compulsory licensing application at a stage when there was controversy about the hearing matter. Natco had also apparently rushed into this matter without completing its homework in Nepal, and it could not substantiate its case for the grant of compulsory licence on public health grounds.

[119] C.H. Unnikrishnan, 'Natco withdraws plea on making patented cancer drugs', Mint: *The Wall Street Journal*, Sep 28 2008 at http://www.livemint.com/2008/09/28214903/Natco-withdraws-plea-on-making.html

[120] Shamnad Basheer, 'Breaking News: Natco Withdraws "Doha" Compulsory Licence Application' on *SpicyIP* (September 28, 2008) at http://spicyipindia.blogspot.com/2008/09/breaking-news-natco-withdraws-doha.html

VI. Conclusion

In conclusion, one possible way of maintaining Indian exports at their current level is through the strategic use of compulsory licensing provisions which are incorporated in Indian law. I have analysed this potential in the light of early compulsory licensing instances. Natco's application for a compulsory licence highlights the ambiguities in the law and procedure. Contrary to the general assumptions, the system did not work efficiently in this first case for a variety of reasons which could be attributed to the Patent Office, patent law, the applicant and patent holders. However, the main reasons were procedural ambiguities and the lack of appropriate homework by the applicant

I have argued that both the international framework (WTO *Waiver Decision 2003*) and the domestic rules (Indian compulsory licensing provisions) will not help in achieving the objectives of the *Doha Declaration 2001*. Four main reasons are cited here to support this position. First, the complexity of rules is a vital constraint and it operates both on the levels of treaty law and domestic regulation. Second, pharmaceutical firms view the export potential in terms of market size and the profits involved in such supply. Because of the complexity of rules, and fragmented markets, the firms may be less inclined to engage in export oriented production if their commercial expectations are largely unmet. Third, the chances of supplies being available becomes more unlikely especially if the firms have to make specific technological investments to produce the drugs required for a limited time in a restricted territory. Such technological investment is essential to the manufacture of new drugs which are constantly in demand in most of the African countries. Fourth, the Indian government lacks the political will or enthusiasm to engage in the wide scale use of Section 92A.[121] The Indian government has a vested interest in integrating into the global economy and trading network.

[121] Sanjeev Choudhary and Khomba Singh, 'Government may use Compulsory Licensing for Drug Companies only in Emergency', *The Economic Times*, 3 April 2008, at http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare__Biotech/Healthcare/Govt_may_use_compulsory_licensing_for_drug_companies_only_in_emergency/articleshow/2921237.cms

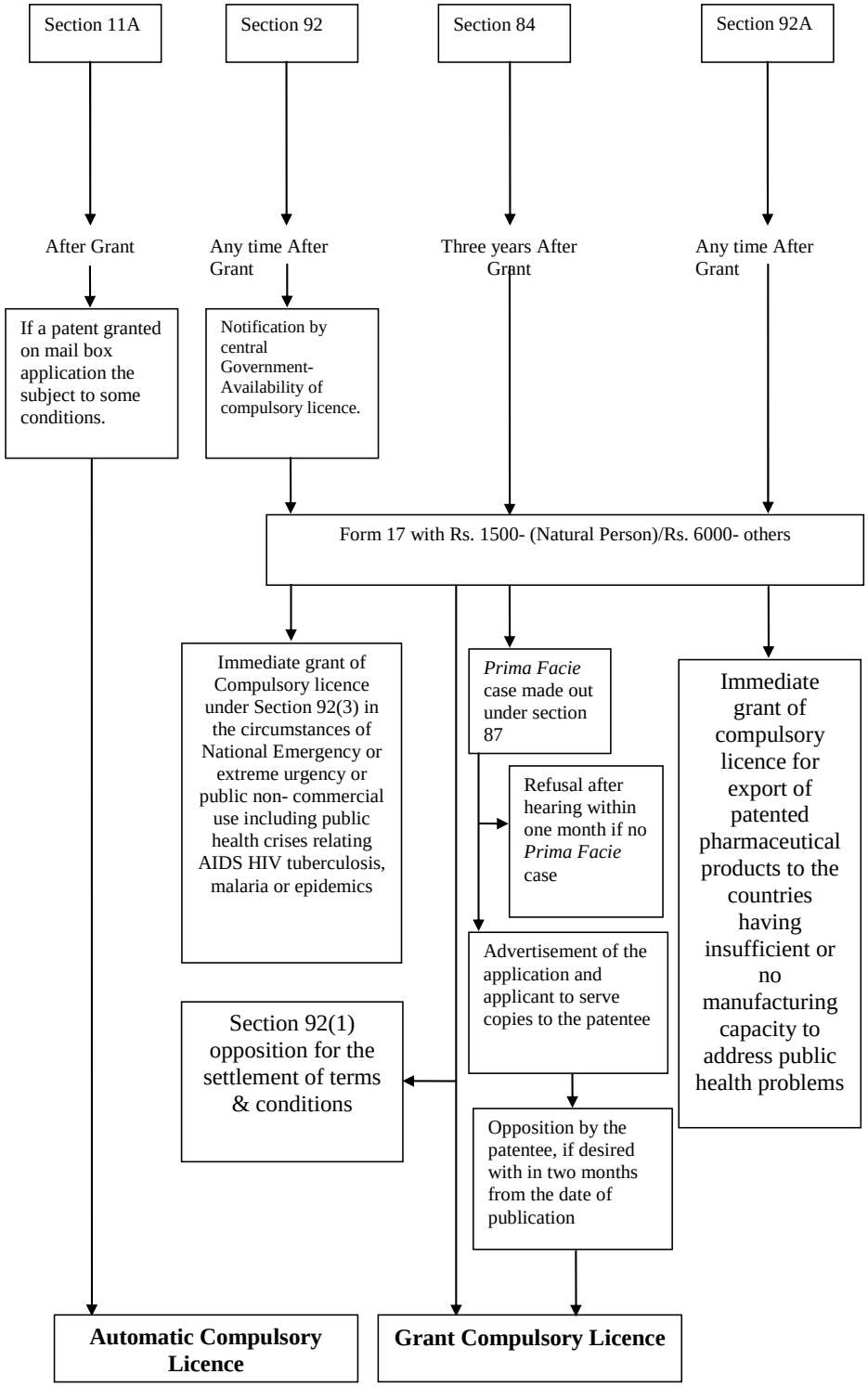

Figure 4.1 Four Modes of Compulsory Licensing under the Patents Act 1970 (India) as amended at 2005