Overhauling Indian Intellectual Property Rights Regime With Special Reference To Compulsory Licensing

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Abstract

Intellectual Property Laws should be used as a tool to strike a balance between the interests of the creator or inventor and the interests of the public. However, after becoming a signatory to The Agreement on Trade-Related Aspects of Intellectual Property Rights, which demanded a drastic change in the Indian Patent Regime, and subsequently amending the Indian Patents Act, 1970 in accordance with the Agreement, India has rarely used patents as an interventionist tool for ensuring the welfare of its citizens as well as the citizens of its fellow Third-World Countries. This assertion holds much water regarding the issuance of compulsory licenses. Compulsory licenses are licenses given by a government authority to a third-party to use intellectual properties including patents, inter alia, to ensure public welfare. They can be used as a crucial interventionist tool. Though there is a necessity for rendering a large number of compulsory licenses, in the Post-TRIPS era, India has issued only one compulsory license, so far.[1] Hence, it becomes essential to diagnose the problem with the Indian Patent Law Regime pertaining to the issuance of compulsory licences. Amid the pandemic, this diagnosis becomes more crucial.

Keywords: *TRIPS Agreement, Compulsory Licensing, Doha Declaration, Intellectual Properties, Patents.*

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[1] Mansi Sood, *Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India* 6 NUJS L.Rev. 99, 104 (2013)

I. Introduction

The discussion pertaining to compulsory licensing has come to the fore owing to the prevailing COVID-19 pandemic. It has become a commonplace for scholars and jurists to urge the Union Government to invoke compulsory licensing provisions to ensure the accessibility of the people to vaccines and other essential drugs like Tocilizumab, Remdesivir, etcetera for effectively combating the pandemic.[2] The same has been advocated by the Parliamentary Standing Committee on Commerce too.[3] Even the Apex Court flagged this issue for the consideration of the Union Government.[4] These exhortations merit serious consideration. Intellectual Property Laws should be used as a tool to strike a balance between the interests of the creator or inventor and the interests of the public. As rightly pointed out by Prof. Michael Kern, patents are an interventionist tool, which is to ensure community welfare.[5] However, after becoming a signatory to The Agreement on Trade-Related Aspects of Intellectual Property Rights, which demanded a drastic change in the Indian Patent Regime, and subsequently amending the Indian Patents Act, 1970 in accordance with the Agreement[6], India has rarely used patents as an interventionist tool for ensuring the welfare of its citizens as well as the citizens of its fellow Third-World Countries.[7] This assertion holds much water regarding the issuance of compulsory licenses. Compulsory licenses are licenses given by a government authority to a third-party to use intellectual properties including patents, inter alia, to ensure public welfare.[8] They can be used as a crucial interventionist tool. Though there is a necessity for rendering a large number of compulsory licenses, in the Post-TRIPS era, India has issued

[2] Among the many articles published in this regard in various Newspapers and Journals, the authors cite two as illustrations here: Amitendu Palit, *Fight Covid with compulsory licensing,* FINANCIAL EXPRESS (May 08, 2021, 4:30 AM), https://www.financialexpress.com/opinion/fight-covid-with-compulsory-licensing/2248068/, Chintan Bharadwaj and Sanat Prem*, COVID-19 Vaccine: A Case of Compulsory Licensing for Social Utility!* 3853761 SSRN (2021).

[3] DEPARTMENT RELATED PARLIAMENTARY STANDING COMMITTEE ON COMMERCE, REVIEW OF THE INTELLECTUAL PROPERTY RIGHTS REGIME IN INDIA 57, 58 (Rajya Sabha Secretariat, New Delhi, 2021).

[4] IN RE : DISTRIBUTION OF ESSENTIAL SUPPLIES AND SERVICES DURING PANDEMIC, SUO MOTO WRIT PETITION (C) NO.3/2021, order dated 27.04.2021.

[5]ELIZABETH VERKEY, LAW OF PATENTS 367 (EBC Publishing (P) Ltd., Lucknow 2012).

[6] A. Kamiike, *The TRIPS Agreement and the Pharmaceutical Industry in India*, 32(1) J. Interdiscip. Econ. 95–113 (2020).

[7] Mansi, *infra* note 8.

[8] ELIZABETH, *supra* note 4.

only one compulsory license, so far.[9] Hence, it becomes essential to diagnose the problem with the Indian Patent Law Regime pertaining to the issuance of compulsory licenses. Amid the pandemic, this diagnosis becomes more crucial. The author through this paper attempts to examine the Indian Intellectual Property Rights Regime with special reference to compulsory licensing and so as to lay out certain suggestions to rationalize the existing provisions on compulsory licensing.

II. Compulsory Licensing Under The Indian Patent Regime

Patents can be broadly defined as, "as statutory grants of monopoly for working an invention and vending the resulting product".[10] Only the patentee, or any person or institution authorized by her, can manufacture and sell the patented product, or can use or imitate the patented process for a stipulated period of time.[11] The rights conferred on the patentee can be abused by her through various means. She can staunchly refuse to grant licenses or can impose patently unfair terms on the licensee or can impose rigorous restrictions on the use of the patented articles.[12] The exploitation of rights by the patentee may make the market anti-competitive, and may also lead to selling the manufactured patented products at exorbitant prices, which can result in inaccessibility due to people's unaffordability. In such cases, governmental intervention, through various mechanisms, becomes inevitable. Compulsory licensing is one such interventionist tool with the government, which attempts to strike a balance between two objectives: rewarding inventions and making them accessible to the masses before the termination of term of patent.[13]

Though the origin of compulsory licensing is often traced back to the United Kingdom's Statute of Monopolies enacted in 1624, the concept of compulsory licensing became popular in European countries only in the 19th century with the emergence of anti-patent movements

[9] Mansi Sood, *Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India* 6 NUJS L.Rev. 99, 104 (2013)
[10] JUSTICE N. RAJAGOPALA AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW 11 (Government of India, New Delhi, 1959).
[11] *Id*.
[12] ELIZABETH, *supra* note 4.
[13] *Id.*

in those countries.[14] A clear provision pertaining to compulsory licensing first appeared in the UK Patent Act of 1883.[15] Section 22 of the Act, enables the Board of Trade to order the patentee to grant licenses to any person petitioned for the patent, when the patentee refused to grant license to others and consequently the refusal either led to, non-working of the patent in UK or a situation wherein the reasonable requirements cannot be catered to or the prevention of using or working the invention to the best advantage.[16] This provision influenced various other countries to utilize compulsory licensing as an interventionist tool.[17] Article 5(A)(2) of the Paris Convention insisted the signatory nations have provisions for issuing compulsory licenses so as to avoid abuses or misuses of monopoly rights conferred on the patentee.[18]

From the 1850s the British Government started enacting patent laws for India, which were largely based on the contemporary patent laws of the United Kingdom.[19] Indian Patent Law, being heavily influenced by the British Patent Law initially, till the enactment of the Patents Act, 1970, it legally recognized and provided patents for products as well as processes. The concept of compulsory licensing was introduced in India by the Invention and Design Act, 1883. The provision providing for issuance of compulsory licensing in the Act was analogous to Section 22 of UK Patent Act of 1883.[20] Section 22 of the Indian Patents and Designs Act, 1911 also provided for compulsory licensing by adding some additional grounds to the aforementioned three grounds for the issuance of compulsory license.[21] However, no compulsory licence had been issued during colonial rule.[22] In 1947, a panel constituted by the Union Government to make some recommendations for the development of pharmaceuticals, drugs and fine chemicals in India, pointing out to the abuse and misuse of patent law done by foreign companies, asserted in their report that it was practically impossible to acquire

[14] Deli Yang, *Compulsory Licensing: For Better or For Worse, the Done Deal Lies in the Balance* 17 J. Intellect. Prop. Rights 76, 77 (2012)
[15] Patents, Designs & Trade Marks Act, 1883, § 22, No. 46 & 47, Acts of Parliament, 1883 (UK).
[16] *Id*.
[17] Deli Yang, *supra* note 13.
[18] Paris Convention for the Protection of Industrial Property, as last revised at the Stockholm Revision Conference, Mar. 20, 1883 21 U.S.T. 1583.
[19] G. Krishna Tulasi and B. Subba Rao, *A detailed study of patent system for protection of inventions* 70 (5) Indian J Pharm Sci 547 2008.
[20] *Id*.
[21] Indian Patents and Designs Act, 1911,§ 22, No. 2, Acts of the Governor General of India in Council, 1911 (India).
[22] Sudip Chaudhuri, *TRIPS and changes in Pharmaceutical Patent Regime in India* Working Paper No. 535 IIM Calcutta 29 (2005).

compulsory license under Section 22 of the 1911 Act due to the wording of the provision, and alluding to the amendment made by the UK Parliament on the provision providing for compulsory licensing in UK Patent and Designs Act of 1907, largely based on which Indian Patents and Designs Act, 1911 was enacted, the Report urged the government to make necessary amendments taking cue from there.[23] Similar suggestions were made by the Interim Report submitted by the Patents Enquiry Committee in 1949.[24] On the insistence of those two reports necessary amendments were made to Indian Patents and Designs Act, 1911 in 1950 and 1952.[25] However, even after the two amendments the procedure to obtain compulsory licenses remained elaborate and cumbersome. The patentees could object to the grant of compulsory licenses and they were provided with remedies such as appealing against the decisions taken by the controller to provide patents, which permitted them to indefinitely prevent or delay the use of granted compulsory licenses.[26] Because of these only two compulsory licenses were granted till 1972.[27] In 1959, Ayyangar Committee, which was constituted to review the Patent Laws of India, submitted its report to the Union Government. The report rightly diagnosed the problems faced by developing countries like India due to the large number of foreign-owned patents and suggested compulsory licensing as one of the two effective remedies to sort them out.[28] The Committee recommended the elimination of pharmaceutical product patents, which in practice would establish automatic compulsory licensing for pharma-products.[29] The report had a substantial influence on the Patents Act, 1970.

The coming into force of the Patents Act, 1970 marked the beginning of a new Chapter in the Indian Pharmaceutical Industry. Post the Indian Patents Act, 1970, the ghost of product patents having been completely abolished with respect to Pharmaceutical products, fertile ground was laid for the rise of new pharmaceutical companies for the generic production of medicines for

[23] THE PANEL ON FINE CHEMICALS, DRUGS AND PHARMACEUTICALS, REPORT OF THE PANEL ON FINE CHEMICALS, DRUGS AND PHARMACEUTICALS 15 (Department of Industries and Supplies, 1947).
[24] JUSTICE N. RAJAGOPALA AYYANGAR, supra note 9, at13.
[25] CHAUDHURI, *supra* note 21, at 28
[26] *Id*.
[27] *Id*.
[28] JUSTICE N. RAJAGOPALA AYYANGAR, supra note 9, at 47.
[29] Dipika Jain and Jonathan J. Darrow, *An Exploration of Compulsory Licensing as an Effective Policy Tool for Antiretroviral Drugs in India* 23 (2) Health Matrix (2013).

one of the largest countries of the World and for the third world countries at large[30]. In the product patent regime previous to the coming into force of the 1970 Act, large monopolies were created with little to no incentive for the domestic pharmaceutical companies to go for generic production[31].

International Pharmaceutical companies having huge investment in the Research and Development front exploited the Indian market in the backdrop of stringent and detrimental patent regimes. Indian Pharmaceutical companies with smaller capital frameworks were positioned in a grave situation where in spite of huge demand for affordable medicines, the pharmaceutical companies were handicapped as they could not put in capital investment anywhere comparable to the International pharmaceutical companies which were dominating the market[32]. This predicament prevailed irrespective of the urgent need of a third world country like India to provide its population with affordable medicines[33].

This scenario was overhauled as soon as the Patent Act, 1970 came into force. This overhaul led to the rise of an Indian pharmaceutical industry which integrally turned the position in which the India pharmaceutical market was placed. The Indian Pharmaceutical industry rose to the extent that prices of medicines got reduced exponentially and the Indian Pharmaceutical industry which did now have the know-how to supply to the domestic market grew to the extent that it became one of the great messiahs to supply affordable medicines to other third world countries[34][35][36].

Post the Patents Act, 1970, Indian pharmaceutical companies reverse engineered patented medicines and rose to great heights. This rise of the Indian pharmaceutical industry irked many

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[30] Archa Saran, *India: A Changing Regime - India's Tryst with January 1, 2005* (November 15, 2004), https://www.mondaq.com/india/technology/29573/a-changing-regime--indias-tryst-with-january-1-2005
[31] Chaudri, *supra* note 21, at 25-38
[32] FOURTH PEOPLES' COMMISSION, REPORT ON REVIEW OF LEGISLATIONS AMENDING PATENTS ACT 1970 (National Working Group on Patent Laws, 2004).
[33] Fourteenth Loksabha Session 4, Combined discussion on the Statutory Resolution regarding disapproval of Patents (Amendment) Ordinance, 2004 (No.7 of 2004) and the Patents (Amendment) Bill, 2005, (daily ed. 22nd March 2005 (statement of Mr Murasoli Maran)
[34] Chaudri, *supra* note 21, at25-38
[35] FOURTH PEOPLES' COMMISSION, REPORT ON REVIEW OF LEGISLATIONS AMENDING PATENTS ACT, 1970 17-21 (National Working Group on Patent Laws, 2004)..
[36] Archa, *supra* note 29.

International monopolies which culminated in the TRIPS. One of the most critical aspects of the TRIPS with respect to the Indian scenario was that the status quo of no product for the pharmaceutical industry was turned upside down. Thus the scope for generic production was scuttled at the very core. The generic Pharmaceutical industry of India got destroyed and a stringent Patent regime was established.

There are a number of arguments brought to fore by various fronts that TRIPS was forced upon by the Developed Countries upon the Third World Countries through a number of institutions including WTO[37]. After TRIPS was agreed upon by the Third World countries, apprehensions grew from the Third World countries like India that TRIPS established a very stringent IP regime which would push them in a dire condition of unavailability of affordable medicines even at the times of health emergencies - endemic like scenario[38]. This apprehension grew stronger and the Third World countries valiantly raised this position before the TRIPS members and WTO. Thus a discourse was created around the issue of access to affordable medicines at the time of health emergencies to Third World countries. Third World countries like India apprehended that though the TRIPS encapsulates certain exceptions to the stringent IP regime which could be used in the circumstances emergencies, when the Third World countries actually face the Health emergencies the exceptions enlisted turn out to be futile since there is an acknowledgement by the Third World countries that the Developed Countries would object and try to scuttle the initiative of a Third World countries to relax the stringent IP regime set out by the TRIPS in the irrespective of the realities prevailing in those countries[39].

Article 31 of the TRIPS agreement introduced "flexibilities" which are essentially exceptions from the IP Protection Regime that TRIPS envisaged. These flexibilities can be availed by the member countries in order to deal with various contingencies that may arise out of the

[37] Fourteenth Loksabha Session 4, Combined discussion on the Statutory Resolution regarding disapproval of Patents (Amendment) Ordinance, 2004 (No.7 of 2004) and the Patents (Amendment) Bill, 2005, (daily ed. 22nd March 2005 (statement of Mr Rupinder Pal).
[38] *Id.*
[39] CARLOS CORREA AND DUNCAN MATTHEWS, DISCUSSION PAPER ON THE DISCUSSION PAPER THE DOHA DECLARATION TEN YEARS ON AND ITS IMPACT ON ACCESS TO MEDICINES AND THE RIGHT TO HEALTH (United Nations Development Program, 2011).

application of the TRIPS including: failure of the Patents to serve public interest in normal and especially in extraordinary circumstances.

Though this flexibility was provided by TRIPS, post-TRIPS many Third World countries were apprehensive about the high price they have paid for the harmonisation of IP laws. Many Third-World countries have expressed their grievance that the flexibilities provided would prove inadequate in situations of emergency/dire circumstances[40]. One of the most significant forums where these apprehensions were raised was the Doha Inter Ministerial Conference, 2001. In order to allay the apprehensions a strongly worded instrument famously called as 'Doha Declaration' was issued at this Conference which embodied at its core the position that every member would be free to enjoy the "flexibilities" in situations of emergency or dire circumstances, on terms and conditions which they are free to set for themselves.

"*Thirdly, we must take note of the awakening of the conscience of humanity, which was helplessly watching while millions died and while millions more continued to suffer in silence because of HIV/AIDS. In mobilising this international public opinion, India, along with Brazil and about 55 African countries, took the lead and the result was the path-breaking Doha Declaration on TRIPS and Public Health. This Declaration provides flexibilities and there is a need to make use of them to the fullest possible extent in our law."*

One of crucial aspect that Doha Declaration achieved is that it strived to allay the core issue that formed the base of the Third World apprehension against the TRIPS that is irrespective of the promise embodied by Article 31, the lack of clarity regarding the modus operandi that a Third World country could embark upon to utilise the Article 31.

Through Doha Declaration clear emphasis was laid and the member countries were given substantive freedom with respect to the procedure that they can follow in order to relax the rigors of the IP regime in the times of emergencies.

Paragraphs 5(b) and 5(c) of the Doha Declaration on the TRIPS Agreement adopted on 14th November 2001 declared:

[40] FOURTH PEOPLES' COMMISSION, *supra* note 34, at 17-22.

"(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."

After the Doha Declaration began the substantive initiatives in India to bring in amendment in the Patent Act, 1970 so as to make it TRIPS compliant. The two most significant amendments in this regard are the Patents (Amendment) Act, 2002 and the Patents (Amendment) Act, 2005.

The Patents (Amendment) Act, 2002 attains significance in this report as it is the enactment which intended to reframe the Chapter XVI of the Patents Act, 1970 which dealt with the matter of Compulsory licensing. The Patents (second Amendment) Bill, 1999 which matured into the Patents (Amendment) Act, 2002 was analysed by a Joint Parliamentary Committee (JPC) for about two years[41]. In those two years, the JPC had the privilege of observing the international dialogue culminating in the making of the Doha Declaration. The JPC also acknowledged this and discussed it in its proceedings but it miserably failed to imbibe the essence of the dialogue into the legislation. This failure is expressed from the fact that the JPC though cared to reframe the substitution proposed by the Bill but did not propose any change with regard to the procedure that needs to be followed in order to get the Compulsory license under section 84. Section 87 of the Patent Act, 1970 lays out the procedure that is to be followed while granting Compulsory License under section 84. This procedure read in whole requires very strict and time consuming steps to be adhered to while granting the Compulsory License. It requires publication of the application for compulsory license in the gazette, serving of copies of application to the patentee, grant of two month period to raise any objection against the application from the date the application is published in the journal, then conduct of a mini-trial to decide upon the objections raised in the raised against the application

[41] PARLIAMENTARY JOINT COMMITTEE, REPORT OF THE PARLIAMENTARY JOINT COMMITTEE ON THE PATENTS (SECOND AMENDMENT) BILL, 1999 (Parliament of India 2001)..

for Compulsory License. Many scholars argue that this modus operandi laid down to get Compulsory License is overtly cumbersome and is in utter disregard of the letter and spirit of the Doha Declaration on TRIPS and Public Health and also it is something even not required at all in the light of the requirements set forth by the TRIPS agreement regarding grant of Compulsory License[42].

Thus eventually, India brought an amendment to make the Indian patent law TRIPS agreement compliant but it somehow ended up making India a TRIPS over-complaint country. Though certain dissents were made in the JPC as well in the Lok Sabha with regard to the subject matter of procedure to be followed in grant of Compulsory License, none of those dissents acknowledge flawed modus operandi imbibed in the Indian patent law. The Patents (second Amendment) Bill, 1999 thus finally matured into an Act without any substantial changes being made to the modus operandi regarding grant of compulsory license.

The next major amendment was the Patents (Amendment) Act, 2005. One of the aims of this amendment was to introduce product patents in all fields of technology (that is, drugs, food and chemical since product patent protection already exists for all other fields), as per Article 27 of the TRIPS agreement to introduce a provision for enabling the grant of compulsory license for export of medicines to countries which have insufficient or no manufacturing capacity to meet emergent public health situations (permissible under paragraph 6 of the Doha Declaration on TRIPS and Public Health).

Section 5 of the Patents Act, 1970 relating to inventions where only methods or processes of manufacture are patentable, was omitted by section 4 of the Amendment Act.

"5. Inventions were only methods or processes of manufacture and substances when produced by such methods or processes patentable — In the case of — In the case of inventions —

(a) claiming substances intended for use, or capable of being used, as food or as medicine or drug or,

[42] Chaudri, *supra* note 21, at 28.

(b) relating to substance prepared or produced by chemical process (including alloys, optical glass, semi-conductors and inter-metallic compounds,

the patent shall be only in respect of claims for the method or process of manufacture and in respect of claims for the substances when produced by such method or process."

Further section 53 was amended which made the term for a patent to be of 20 years.

III. India's Failure To Accommodate Flexibilities In Trips And Ensuing Consequences

Post TRIPS after the Indian patent law was made over-compliant to TRIPS , the base of the vibrant Indian generic pharmaceutical production crumbled.[43] The Indian pharmaceutical companies which were earlier successfully exporting essentially medicines to other countries after satisfying the domestic needs, post 2005 faced difficulties in even meeting the demands of the domestic market for affordable medicines. After a phase of struggle, the many domestic pharmaceutical companies closed down and those who remained in the business embarked on a path radically different from the earlier one. Due to the effect of TRIPS compliance the Indian pharmaceuticals changed their strategy from being generic producers to producer-partners i.e. they created ties with big Pharma companies and manufactured their patent medicines. This marked the overturn of Indian pharma companies approach towards production of medicines post the TRIPS compliance.

IV. A Roadmap For Effective Accomodation Of The Flexibilities

The reasons for the destruction of the domestic generic production was inevitable post TRIPS agreement but what made this destruction more worse is the fact that India did not capitalise on the flexibilities offered by the TRIPs agreement read with the Doha Declaration. Though the substantial points expressed in the Article 31 of TRIPS agreement read with the Doha Declaration was imbibed in the Patents Act, 1970, no changes were made to ease the procedure

[43]Ajay Prakash et al., *Intellectual property rights and Indian pharmaceutical industry: Present scenario*, 50 Indian J. Pharmacol. 57–60 (2018).

that is to be followed in the grant of Compulsory License. The stringent compulsory license procedure which was part of the patent law which had comparatively very high incentives for generic production continued to be present unchanged even when the many integral aspects of the law were drastically changed. This expressed utter carelessness and lack of will and thought process regarding the grave threat the cumbersome and burdensome procedure for grant of Compulsory license will result in. The result of this ignorance after more than 15 years of coming into force of TRIPs is blatantly clear - only one successful case of Compulsory License and only a handful of attempts towards Compulsory License.

Thus it is time an overhaul of the procedure laid down in the patent law regarding the grant of compulsory License be made. The following are the changes that is proposed in order to remove the bottlenecks present in the Patents Act, 1970:

1. One of the most problematic things that is acknowledged with respect to the procedure for grant of compulsory license is that there is no time frame that is set for the processing of the application. This lack of time frame has resulted in indefinite time being taken by the Controllers to process the applications and thereby greatly disincentivizing attempts towards compulsory licensing. And further is indefiniteness is in complete disagreement to the kind of importance that is attached to the subject matter of compulsory license. Hence it is proposed to amend section 84 of the Patents Act, 1970 which relates to the role of the Controller regarding grant of compulsory license making it mandatory for the Controller to grant compulsory license within a set time frame of 30 days.

2. The next main issue with the current procedure is that it requires too many time consuming steps to be followed with regard to grant of compulsory license. Section 87 of the Patents Act, 1970 lays out of burdensome procedure which includes publication of the application for compulsory license in the gazette, serving of copies of application to the patentee, grant of two month period to raise any objection against the application from the date the application is published in the journal, then conduct of a mini-trial to decide upon the objections raised in the raised against the application

for Compulsory License. Thus it is proposed to delete this entire procedure and reframe a new procedure to be followed with regard to grant of compulsory license.

A new section is proposed to be added to the Patents Act, 1970 which lays out an efficient procedure regarding grant of compulsory license within the time period of 30 days. This procedure eliminates the unnecessary requirement of publication in the official journal. And then put forward a simple four fold step which includes (1) application; (2) serving of copies of the application to the interested parties; and (3) raising of objections against the application; and finally (4) a hearing to finally decide whether to grant or deny compulsory license. All these steps are to be assigned an appropriate time frame so as to finish the entire procedure within a 30 days period. This reduction in time period for the respective steps is substantiated by the fact that new age technologies can be employed so as to expedite the process as much as possible. The presence of technologies like email and virtual hearing in the background of dire need to decide the matter at the earliest justifies the considerable less time allocated to respective steps.

3. The next major issue that is argued by many experts in the field is that onerous requirements are set forth in a compulsory license process by burdening the applicant to prove that: (1) the patented medicine is not affordable; (2) the production doesn't match the demand; (3) there is great public interest in the grant of compulsory license etc. The applicant is required to provide sufficient data in order to provide for the above requirement but at the same time there is hardly any comprehensive system that is in place to check over the price, production and other related matters with regard to a patented medicine. Thus it is proposed that an independent institute be established whose sole duty shall be to work upon the matter related to affordability, accessibility and production of a patented medicine. This would lessen the burden of the applicant and further would put in place a system which the Controller deciding upon the matter of grant of compulsory license could steadfastly rely on.

4. The last of the pertinent changes required concerns with giving finality to the decision of the Controller concerning grant of compulsory license. Unending litigation could only hamper the critical needs of the country in this matter and also since the whole

decision of the Controller is based upon data put forth by the Institute the requirement for raising an appeal against the decision of the controller is very narrow. Thus, a general ban on appeal against the decision of the Controller concerning compulsory license is proposed. The two exceptions to ban on appeal are with regard to the decision taken by the Controller regarding revocation of compulsory license and any substantial disregard of principles set forth in Chapter XVI of the Patents Act, 1970.

V. Conclusion

Article 1 of the TRIPS agreement states that no member country is required to give effect to the TRIPS agreement more extensive than that is required by it. Further it states that the member countries are free to lay out their own methods for implementation of provisions of the TRIPS agreement based on their legal system and practice. Further the Doha Declaration on TRIPS and Public Health held that nothing in the TRIPS will obstruct any country's endeavor to enjoy the flexibility provided in the TRIPS agreement, at the time of health emergency and other related events. Irrespective of this position, no initiative was taken to acknowledge and amend the procedure that is laid out in the Patents Act, 1970 regarding grant of compulsory license which is utterly cumbersome and in complete disregard to the imminent national interest that is depended on it. All these arguments are substantiated by the fact that India managed to see only one successful compulsory license post 2005. Now at this point of time, after more than 15 years of experience with the inefficient procedure, it is time we reframe the procedure as an entire breath so as to stay true to the position that India took so as to achieve the Doha Declaration.