

IN THE SUPREME COURT OF GERM-MANY
ORIGINAL JURISDICTION
CIVIL WRIT PETITION NO. _____ OF 2013

IN THE MATTER BETWEEN

Medimax Inc.Petitioner

Versus

Union of Germ-many & Medirip....Respondents

PETITION UNDER ARTICLE 32 OF THE CONSTITUTION OF
GERM-MANY

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ABBREVIATIONS

- &AND
- ¶PARAGRAPH
- AIR.....ALL INDIA REPORTER
- Anr.....ANOTHER
- Assn.....ASSOCIATION
- Co.COMPANY
- Corp.CORPORATION
- Doesn't.....DOES NOT
- Edn.....EDITION
- EMREXCLUSIVE MARKETING RIGHTS
- Etc.....ETCETERA
- Govt.GOVERNMENT
- HON'BLE.....HONOURABLE
- Ibid.IBIDEM
- Inc.INCORPORATION
- ITC.INDIAN TOBACCO COMPANY
- i.e.THAT IS
- K.S.EKERALA STATE EDUCATION
- Ltd.LIMITED
- Ors.....OTHERS
- Rly.RAILWAY
- Rs.RUPEES
- SCSUPREME COURT
- Sd/-.....SIGNED
- TRIPS.....
.TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS
- U.S.UNITED STATES
- WTO.....WORLD TRADE ORGANIZATION
- v.VERSUS

INDEX OF AUTHORITIES

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2. *Ashutosh Gupta v. State of Rajasthan* AIR 2002 SC 1533.
3. *Bharat Hydro Power Corpn. Ltd v. State of Assam* (2004) 2 SCC 553.
4. *Bajaj Auto Ltd. v. TVS Motor Company Ltd.* 2008 (36) PTC 417 (Mad.).
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13. *Hamdard Dawakhana v. Union of India* AIR 1960 SC 554.
14. *In re Delhi Laws Act* AIR 1951 SC 332.
15. *Ishwari Khetan Sugar Mills (P) Ltd. and Ors. v. State of Uttar Pradesh & Ors.* 1980 SCR (3) 331.
16. *ITC Bhadrachalam Paper Boards v. Mandal Revenue Officer* (1996) 6 SCC 634.
17. *K. Thimmappav. Chairman, Central Board of Directors* AIR 2001 SC 467.
18. *K.S.E. Board v. Indian Aluminium* AIR 1976 SC 1031.
19. *Khoday Distilleries Ltd. and Ors.v. State of Karnataka & Ors.* (1995) 1 SCC 574.
20. *M.P. High Court Bar Association v. Union of India* (2004) 11 SCC 766.
21. *Maneka Gandhi v. Union of India* AIR 1978 SC 597.
22. *Master Jishnu G v. Bruhat Bangalore Mahanagara* W.P.No.37197/2011.
23. *Muralidhar v. State of Rajasthan* AIR 2000 Raj 170.
24. *Natco v. Bayer Compulsory License Application No. 1 of 2011.*
25. *Novartis AG v. Union of India* 2007 (4) MLJ 1153.
26. *Organo Chemical Industries v. Union of India* AIR 1979 SC1803.
27. *Queen v. Burah* 5 IA 178 (1878).
28. *Sai Traders A Proprietary Concern v. State Of Goa & Ors* 2006(4) Bom.C.R.1.
29. *Shiv Dutt Rai Fateh Chand v. Union of India* AIR 1984 SC 1194.
30. *Society for Un-aided Private Schools of Rajasthan v. Union of India & Anr.* AIR 2012 SC3 445.
31. *Southern Pharmaceuticals & Chemicals Ltd. v State of Kerala* AIR 1981 SC 1863.
32. *State of Bihar and Ors. v. Shree Baidyanath Ayurved Bhawan Private Ltd. &Ors.*AIR 1996 SC 2829.
33. *State of Bombay v. F.N. Balsara,* AIR 1951 SC 318.

34. *State of Bombay v. RMD Chamar Baughwala* AIR 1957 SC 699.
35. *State (Delhi Adm.) v. V.C. Shukla* AIR 1980 SC 1382.
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38. *State of Rajasthan v. Vatan Medican and General Store* AIR 2001 SC 1937.
39. *State of Tamil Nadu v. K. Sabanayagam* AIR 1998 SC 344.
40. *Sukhwinder Pal Bipan Kumar v. State of Punjab* AIR 1982 SC 65.
41. *Ujagar Prints etc v. Union of India & Ors.* 1989 (3) S.C.C.488.
42. *Union of India v. Cynamade India Ltd.* AIR 1987 SC 1802.
43. *Union of India v. M.V. Valliappan* AIR 1999 SC 2526.
44. *V. Manioka Thevar v. Star Plough Works, Melur* AIR 1965 Mad 327.
45. *Vasu Dev Singh and Ors. v Union of India & Ors* Appeal (Civil) 4688 of 2006.
46. *Welfare Association A.R.P., Maharashtra and Anrv. Ranjit P. Gohil & Ors.* Civil Appeal No 5168 of 1998.

CONSTITUTIONS REFERRED:

- CONSTITUTION OF INDIA, 1950

CONVENTIONS REFERRED:

- Berne Convention For The Protection Of Literary And Artistic Works, 1886
- Doha Declaration On The Trips Agreement And Public Health, 2001
- Paris Convention For The Protection Of Industrial Property, 1883

- Trade Related Aspects Of Intellectual Property Rights, 1996

STATUTES REFERRED:

- Code of Civil Procedure, 1908.
- The Patents Act,1970.
- The Specific Relief Act, 1963.

STATEMENT OF JURISDICTION

The Petitioner has approached the Hon'ble Supreme Court of Germany under Article 32¹ of the Constitution of Germany.

With all due respect to this Hon'ble Court, The Respondent reserves the right to contest the jurisdiction.

¹ Article 32 of The Constitution of India states:

Art. 32 : Remedies for enforcement of rights conferred by this Part.-

- (1) The right to move the Supreme Court by appropriate proceedings for the enforcement of the rights conferred by this Part is guaranteed
- (2) The Supreme Court shall have power to issue directions or orders or writs, including writs in the nature of habeas corpus, mandamus, prohibition, quo warranto and certiorari, whichever may be appropriate, for the enforcement of any of the rights conferred by this Part
- (3) Without prejudice to the powers conferred on the Supreme Court by clause (1) and (2), Parliament may by law empower any other court to exercise within the local limits of its jurisdiction all or any of the powers exercisable by the Supreme Court under clause (2)
- (4) The right guaranteed by this article shall not be suspended except as otherwise provided for by this Constitution

STATEMENT OF FACTS

- The Republic of Germ-many is a developing country with a significant gap between haves and have-nots. The citizens are afflicted with a number of diseases and there has been a pressure on the govt. to provide affordable medicine to all citizens.
- Ameryana is a developing country which is known for manufacturing life saving drugs.
- Germ-many had acquired notoriety for tripping itself up over TRIPS instrument. It was taken to the WTO Dispute Panel. However, now it has become fairly proficient at gripping it but Germ-many considers it to be ambiguous and unfair.
- Germ-many in order to reduce healthcare costs amended its Patents Act by way of Patents (Amendment) Act, 2012 in November.
- The said Amendment Act deals with the grant of compulsory license of a patented invention. It lays down all the procedural requirements that are to be fulfilled for the grant of license.
- Medimax Inc. (Medimax) a pharmaceutical conglomerate based in Ameryana filed for a patent in Germ-many for a cancer drug and procures the same in August 2009. The drug is sold in Germ-many by the name “Candid”.
- The crude form of NCE (patented product) was made in Ameryana and was thereafter refined and combined with other additives to get the end product.
- In December 2012, Medimax discovered that Medirip a Germ-many based company with its registered office in Germ-many was selling a generic version of their drug called “Placid”.
- Hence, an infringement suit is filed. They seek inter alia, for interim injunction but owing to the amendments, it is denied and the matter directly moves to trial.
- Simultaneously, while the suit is pending Medirip applies for compulsory license saying that “Candid” is not manufactured in Germ-many.
- State of Germ-many issues notification stating that all the patented cancer drugs would automatically be subject to compulsory license and any such patent can be worked by private parties (who apply to the government for permission to use the patent) or the government itself or for public non-commercial use.

- Medimax has now filed a writ petition in the SC of Germany claiming the Amendment to the Patent Act is unconstitutional being inter alia arbitrary and discriminatory.

QUESTIONS PRESENTED

I. Whether providing for grant of compulsory license of patented invention violative of Article 14?

A. *The classification purported in Section ii. whereby only pharmaceutical patent infringement suits are barred from availing interim injunction is reasonable and has nexus with the object of Amendment Act.*

B. *The grant of compulsory license to any applicant on the ground of "patented invention not manufactured in Germany" permits reasonable discrimination to achieve the object of Amendment Act.*

II. Whether the Amendment Act is backed by legislative competence and therefore is not unconstitutional?

III. Whether the Article 301 is violated by the said Amendment Act 2012?

IV. Whether the Amendment Act suffers from the vice of excessive delegated legislation and hence, is unconstitutional?

SUMMARY OF PLEADINGS

I. Whether providing for grant of compulsory license of patented invention violative of Article 14?

The Respondent respectfully submits that the impugned legislation is not violative of Article 14 of the Constitution in letter or in spirit. The classifications provided by the Amendment Act in the form of "patent pharmaceutical infringement suits" and "not manufactured in the territory" are intelligible classification having a rational nexus with the object of the amendment act, i.e. to reduce healthcare costs. Additionally, the exercise of discretion available under the impugned section i (a) and section iii are not unguided or uncanalized as the procedural requisites and the policy of the Government act as sufficient safeguards.

II. Whether the Amendment Act is backed by legislative competence and therefore is not unconstitutional?

The Respondent humbly submits that the Legislature has well within the exercise of its legislative competence enacted the present impugned legislation. Through the impugned legislation, the Legislature has amended the law pertaining to Intellectual Property which is exclusively within its domain. An ancillary effect of the amendment is public health hence it cannot take away the competence of the Legislature. Even if encroachment exists, it is only incidental and not substantial, resultantly the amendment is constitutional.

III. Whether the Article 301 is violated by the said Amendment Act 2012?

The Respondent respectfully submits the impugned legislation does not violate Article 301 of the Constitution. In the present case, the Petitioner is taking recourse of Article 301 in order to avail a fundamental right enshrined under Article 19(1) (g), which is not basically available to the Petitioner. Additionally, even if the right to free of trade, commerce and intercourse is available to the Petitioner, it is not an absolute right. Under Article 302 and 304(b) restrictions to promote public health are permissible under the scheme of the Constitution. Hence, the impugned legislation is constitutional.

IV. Whether the Amendment Act suffers from the vice of excessive delegated legislation and hence, is unconstitutional?

The Respondent humbly submits that the impugned legislation does not provide for delegated legislation. On the contrary, the Respondent submits that the amendment act provides for conditional legislation which is an administrative power and not a ground available to contest the constitutionality of legislation.

PLEADINGS

I. WHETHER THE PROVISIONS OF THE PATENT AMENDMENT ACT, 2012 ARE ARBITRARY AND DISCRIMINATORY, HENCE VIOLATIVE OF ARTICLE 14?

A. Whether providing for grant of compulsory license of patented invention violative of Article 14?

The Respondent humbly submits that the impugned act, i.e. the Patent Amendment Act, 2012 is not violative of Article 14 of the Constitution.

- a) *The classification purported in Section ii. whereby only pharmaceutical patent infringement suits are barred from availing interim injunction is reasonable and has nexus with the object of Amendment Act.*

In order to safeguard the exclusive rights of the patentee, the Patents Act, 1970 provides for various reliefs. One such remedy is the initiation of a patent infringement suit by the patentee against an alleged infringer.² In pursuance of this remedy, the patentee can seek from the court, the grant of interim injunction by proving the essentials required to obtain interim injunction.

The Madras High Court in *V. Manioka Thevar v. Star Plough Works, Melur*³ laid down an important ruling pertaining to grant of interim injunction which was adopted by various later judgments. The court held that:

"An interim injunction will not be granted if the defendant disputes the validity of the grant."

It was further held that:

²The Patents Act, Section 104 (1970).

³ AIR 1965 Mad 327.

"...when from the objection raised by the defendant if it clear that a serious controversy exists as to whether or not the invention claimed by the plaintiff is a new one or a new manufacture of whether or not the invention involves any new inventive skill having regard to what was known or used prior to the date of the patent, courts will not grant an interim injunction restraining the defendant..."

The Supreme Court in the case of *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries*⁴ held that the grant and sealing of the patent does not guarantee the validity of the patent, as is also provided in Section 13(4) of the Act, hence the presumption in favour of the validity of the patent can't be accepted.

Relying heavily upon the above case, the Supreme Court also reiterated that:

*"...though after the amendment of section 48 the patent obtained has more significance but no presumption of validity of the patent can be drawn..."*⁵

Hence, the Respondent humbly submits that various courts through their ruling have shown a trend against the presumption of validity of patents. Hence, since the question pertains to the validity of the patent itself, grant of interim injunction cannot follow.

Though the presumption is not in favour of the validity of the patent, but if the patentee succeeds in fulfilling all the requisites for grant of interim relief, the relief can be granted.

But in the landmark judgment of *Novartis AG v. Union of India*,⁶ the Madras High Court held the following:

"...if interim injunction were granted to the plaintiff, the manufacturing network of the defendant so far as drug is concerned would be dismantled and if due to any problem the plaintiffs could not make available the drug in required quantity in India it would be disastrous for patients. The aspect of price difference between the product of the plaintiff and defendants also influenced the Court."

The Delhi High Court subscribes to the same views as purported above.⁷

⁴ AIR 1982 SC 1444.

⁵ *Bajaj Auto Ltd. v. TVS Motor Company Ltd.* 2008 (36) PTC 417 (Mad.).

⁶ 2007 (4) MLJ 1153.

⁷ *Franz Xaver Humer v. NewYash Engineers* 2nd (1996) 2 Del 791.

This approach adopted by these various High Courts is the very intent of the legislature behind legislating this particular impugned provision. In order to promote public health, all pharmaceutical patent infringement suits have been barred from availing the relief of interim injunction.

This classification made is real and substantial as well as intelligible. It is intended to achieve the object of the Amendment Act, i.e. to promote public health and ensure affordable drugs. Hence, there exists a reasonable nexus between the classification and object sought to be achieved. Hence, this provision is not violative of Article 14 of the Constitution.⁸

The Legislature was mindful of the right of the general public to access life saving drugs and how it might be denied if the injunction were granted. If injunction were granted, the degree of harm in such eventuality would be absolute, i.e. the chances of improvement of life expectancy or even chances of recovery in some cases would be jeopardized. Such injuries to third parties are un-compensable.

The above intent of the Legislature behind legislating this provision is in consonance with a recent judgment of the Delhi High Court, whereby the Court proposed that:

*"...between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life saving drug, the balance has to be tilted in favour of the latter. The damage or injury that would occur to the plaintiff in such case is capable of assessment in monetary terms. However, the injury to the public which would be deprived of the defendant's product, which may lead to shortening of lives of several unknown persons, who are not parties to the suit, and which damage cannot be restituted in monetary terms, is not only un-compensable, it is irreparable."*⁹

The impugned section is in consonance with Article 14 and hence constitutionally valid.

⁸*Union of India v. M.V. Valliappan* AIR 1999 SC 2526; *K. Thimmappa v. Chairman, Central Board of Directors* AIR 2001 SC 467.

⁹*F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Limited* MIPR 2008 (2) 35.

b) The grant of compulsory license to any applicant on the ground of "patented invention not manufactured in Germany" permits reasonable discrimination to achieve the object of Amendment Act.

Patents were originally granted to promote transfer of technology, especially the domestic application of foreign technologies and dissemination of new technologies in the country granting patent. These objectives of granting patents in Germany can be gathered from Section 83 of the Patents Act, 1970.¹⁰ Amongst these general principles, those which define the purpose and working of patented inventions articulate that inventions must be worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay and also that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. It is also clearly laid down that the patent right should not be abused and the patentee should not resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology.

Hence, reading the above three provisions in harmony would show that a patentee is obliged to contribute towards the technological advancement of the Country granting him the patent rights. This is possible only if the production or manufacture of the patented invention takes place in the Country by the patentee himself or by a person licensed by him. Hence, local manufacturing of the patented invention is one of the objectives the Patent Act wishes to achieve.

¹⁰83. General principles applicable to working of patented inventions

Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely,—

- (a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
- (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
- (c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
- (d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
- (e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;
- (f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
- (g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

But, this objective can't be imposed upon a patentee as a matter of obligation nor can this objective be made a requisite for the grant of patent to the patentee. Hence, only a reasonable fetter in the form of compulsory license can be imposed upon the rights of patentee to work as a watchdog. In case, the patentee doesn't himself or through grant of license provide for local manufacturing of the patented invention, the provisions of compulsory license can be attracted.

Hence, in the impugned provision, i.e. Section i (b) whereby, compulsory license can be granted if the patented invention is not manufactured in the territory of Germany does provide for an intelligible classification intended to achieve the object of the Patent Act itself. Hence, it is not violative of Article 14 nor does it suffer from the vice of unconstitutionality.

Section i (b) is also in compliance with the TRIPS Agreement:

The TRIPS Agreement in the relevant part of Article 27 provides that:

Subject to ¶ 4 of Article 65, ¶ 8 of Article 70 and ¶ 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

Hence, the Respondents humbly submit that it would amount to discrimination under Article 27.1 of the TRIPS Agreement if a patent is not granted on ground of non-working in the territory. Hence, importation of a patented invention is permissible.

But, the Controller of Patents held that:

“When the Article 27(1) of TRIPS Agreement is read with the afore-mentioned provisions of TRIPS Agreement and the Paris Convention, it follows that importation of a patented invention shall not result in forfeiture of a patent. However, a reasonable fetter on the patent rights in the form of a compulsory license is very well within the purview of the Paris Convention and TRIPS Agreement, when there is an abuse of patent rights. It is this flexibility that the Parliament have invoked in Chapter XVI of the Patents Act, 1970 by incorporating a provision for grant of compulsory license upon failure to work the invention within the territory of India.”¹¹

¹¹*Natco v. Bayer* Compulsory License Application No. 1 of 2011.

Hence, the Respondents humbly submit that it is important to read Article 27 (1) of the TRIPS Agreement with Articles 2, 7, 8 and 30 of the TRIPS Agreement to understand the full purport of the TRIPS agreement.

Article 7¹² sets out the objectives of the TRIPS agreement, stating that the protection and enforcement of intellectual property rights should result in the promotion of technological innovation and technology transfer. It further states that such technology transfer and dissemination should be for the mutual advantage of producers and users in a manner beneficial to their social and economic welfare, and should create a balance of rights and obligations. It is clear that Article 7 recognises both the private interest of the Patent holder and public interest in transfer or dissemination of technology and creation of balance of rights and obligations.

Article 8 (1)¹³ of the TRIPS allow member countries to adopt measures necessary to promote the public interest in sectors of vital importance to their socio-economic and technological development. Similarly, Article 8 (2)¹⁴ of the TRIPS provides member countries to adopt measures that prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the *international transfer of technology*. TRIPS also provides for exceptions to exclusive rights under Article 30¹⁵ of the TRIPS Agreement, that allows member states to provide limited exceptions to exclusive rights conferred by patents. However, such exceptions should not unreasonably conflict with a normal exploitation of the patent and should not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

From the above, it is clear that Article 7, 8 and 30 of the TRIPS restrict the operation of Article 27 (1) of the TRIPS. However, in order to clear any ambiguity towards the

¹² Article 7: Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of

¹³ Article 8: Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

¹⁴ Article 8: Principles

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

¹⁵ Article 30: Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

interpretation of Article 27 (1) of the TRIPS, Article 2 of the TRIPS becomes imperative as it makes Paris convention as part of TRIPS and provides for compliance of Paris Convention with respect to all member states. It is important that interpretations of articles in the Paris Convention should be used to clarify any ambiguities that exist in TRIPS articles regarding similar subject matter.

Article 5(A) (2) of the Paris Convention for Protection of Industrial Property, 1883 provides that each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

It is fair to conclude that the legislation requiring local working of patents would not be in contravention of TRIPS in light of articles 7, 8 and 30 and explicit reference of Paris Convention under Article 2¹⁶ of TRIPS.

In light of the above submissions the Respondents humbly submit that the impugned section is constitutionally valid as well as in compliance with the international patenting norms.

B. Are the provisions for grant of compulsory license of patented invention arbitrary and unreasonable?

a) The grant of compulsory license to any applicant on the ground of "reasonable requirement of public not met" is reasonable.

Patents confer exclusive negative rights which exclude competition in the manufacture and sale of the protected products and, therefore, control the production and distribution of such products and their prices.¹⁷ However, patent rights are not absolute. Limitations can be imposed on these exclusive rights. The right of States to limit the use of patents through

¹⁶ Article 2: Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

¹⁷ <http://apps.who.int/medicinedocs/documents/s19902en/s19902en.pdf> (Last Accessed on Aug. 2, 2013).

compulsory licences has been recognized in almost all important international agreements dealing with intellectual property rights.

- Article 31 of TRIPS Agreement¹⁸ read with Doha Declaration on TRIPS and Public Health, 2001 [Sub-¶ 5 (b)]¹⁹ provides for compulsory license and also empowers the Member states to formulate their own grounds for grant of compulsory license.
- Article 5 of the Paris Convention for the Protection of Industrial Property, 1883 provides for grant of compulsory license in order to prevent the abuse of the exclusive rights of the patentee.

Under the present impugned Amendment Act, a provision for grant of compulsory license on grounds of "reasonable requirements of public not met" has been provided for.

The Respondent humbly submits that the impugned provision is in consonance with the letter and the spirit of the Constitution. It grants the power to the Controller of Patents to determine whether in a particular case, the grant of compulsory license is called for on the basis of the ground provided for.

The intent of the Legislature in employing the words "Reasonable requirement of public" is to further the object of the Amendment. This provision is majorly focusing upon public interest. Words of such vast ambit have been used in order to cater to various situations which may arise like- non-availability of drugs, high prices, cheap quality, mal-practices adopted by the patentee, prejudice towards functioning of other trade and business, etc.

The Respondents humbly submit that these restrictions on the rights of the patentee are not unreasonable or arbitrary.

The present Supreme Court laid down a test to determine the reasonability of restrictions imposed on rights as follows:

¹⁸ Article 31: Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

¹⁹ 5. Accordingly and in the light of ¶ 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

"The phrase reasonable restriction connotes that the limitation imposed on a person in enjoyment of the right should not be arbitrary or of an excessive nature beyond what is required in the interest of the public. The word reasonable implies intelligent care and deliberation, that is, the choice of the course which reason dictates..."²⁰

Hence, in the present case, the limitation - reasonable requirement of public elucidated upon with the help of the explanation can be termed to be intelligent enough to cater to the object of compulsory licensing. Hence, it is not arbitrary or unreasonable.

With relation to laying down principles or guidelines in the exercise of discretion, the words of Supreme Court are aptly applicable to the present situation:

"...it is not essential that the very section in the statute which confers the power should also lay down the rules of guidance, or the policy for the administrator to follow. If the same can be gathered from the preamble, or the long title of the statute and other provisions therein, the discretion would not be regarded as uncontrolled or unguided and the statute in question will not be held invalid..."²¹

One can gather from the facts of the case that the policy intended to be catered for through the Amendment Act is to promise affordable medicines to the people and reduce health care costs. Hence, these will act as guides in the exercise of discretion.

Moreover, the Amendment has conferred power on a high official, i.e. the Controller of Patents who is not expected to misuse the same but is expected to exercise the power reasonably and rationally.²² Additionally, there are procedural safeguard subject to which the power is to be exercised, such as natural justice, payment of remuneration, provision of appeal to higher authority, etc. to ensure justice.²³

Thus, the Respondent humbly submits that the provision is well within the boundaries of the Constitution.

²⁰Chintaman Rao v. State of Madhya Pradesh AIR 1951 SC 118.

²¹Ch&rakant Saha v. Union of India AIR 1979 SC 314; Organo Chemical Industries v. Union of India AIR 1979 SC 1803.

²²Chinta Langam v. Union of India AIR 1971 SC 474; State (Delhi Adm.) v. V.C. Shukla AIR 1980 SC 1382.

²³Sukhwinder Pal Bipan Kumar v. State of Punjab AIR 1982 SC 65; Maneka G&hi v. Union of India AIR 1978 SC 597

b) *The power with the Government to issue notification for automatic grant of compulsory license does not amounts to excessive discretion and is in consonance with Article 14.*

Under section iii of the impugned legislation, the Government is empowered to issue notification for automatic grant of compulsory licenses under certain circumstances. These circumstances include:- national emergency, extreme urgency and public non-commercial use.

As per the ruling of the Hon'ble Supreme Court, the Respondent submits that broad discretion conferred upon the Government is valid and not violative of Article 14 of the Constitution.²⁴

In the landmark case of *Organo Chemical*,²⁵ the Court elucidated that:

"When power is conferred on high and responsible officers they are expected to act with caution and impartiality while discharging their duties...The vesting of discretionary power in the State or public authorities or an officer of high standing is treated as a guarantee that the power will be used fairly and with the sense of responsibility."

Apart from the fact that the exercise of discretion is by the highest competent authority, the discretion cannot be termed to be unguided or uncanalized as procedural requisites laid down in TRIPS Agreement have been included in the Amendment Act. These procedural requisites along with the policy intended to be implemented by the Amendment Act would therefore give a protecting shield to the Act from the allegations of unconstitutionality.²⁶

Thus, the impugned provision is constitutionally valid.

²⁴*Accountant-General v. S. Doraiswamy* AIR 1981 SC 783.

²⁵*Organo Chemical Industries v. Union of India* AIR 1979 SC 1803.

²⁶*Gram Sabha, Shahzadpur v. State of Punjab* AIR 1982 P&H 33; *Shiv Dutt Rai Fateh Ch & v. Union of India* AIR 1984 SC 1194.

II.WHETHER THE AMENDMENT ACT IS BACKED BY LEGISLATIVE COMPETENCE AND THEREFORE IS NOT UNCONSTITUTIONAL?

The said Amendment Act of 2012 was made under the Patent Act 1970. Therefore the respondents humbly submit that the amendment so made was backed by legislative competence as under Article 246(1) of the Constitution.

The said amendment was made under Entry 49 of List 1. The intention of the Amendment is introduction of compulsory licensing with compliance with the TRIPS Agreement.

Even though here there is no overlapping of powers but even in the case of overlapping of powers the Unions power predominated that of the State.²⁷

The validity of the legislation is challenged on the ground of want of legislative competence and it is necessary to ascertain which entry in the Seventh Schedule lists the legislation is referred to, the court has evolved the theory of pith and substance. If in pith and substance a legislation falls within one entry or the other but some portion of the subject matter of the legislation incidentally trenches upon and might enter a field under another list, the Statute as a whole would be valid notwithstanding such incidental trenching.²⁸

If the substance of enactment falls within the Union List then the incidental encroachment by the enactment on the state list would not make it invalid.²⁹

To ascertain the true character of a law, it must be looked into as an organic whole. It would be a wrong approach to view the statute as a mere collection of sections. To disintegrate it in two parts and then to examine under which entry each part would fall and then to determine which part of it would be valid and which invalid.³⁰

The true nature of the Amendment Act is to put restrictions on a right in exceptional circumstances, since no right can be deemed to be absolute, in the form of compulsory license, whose power resides completely under the Patent Act.

²⁷*Ishwari Khetan Sugar Mills Pvt. Ltd. & Ors v State of Uttar Pradesh & Ors.* 1980 SCR (3) 331.

²⁸*State of Bombay v. F.N. Balsara*, AIR 1951 SC 318.

²⁹*Bharat Hydro Power Corpn. Ltd v. State of Assam* (2004) 2 SCC 553.

³⁰*State of Rajasthan v. Vatan Medican & General Store* AIR 2001 SC 1937.

The power to mould or alter rights and obligations to patent holders can only be done via the patent act and that is the power of the Union.

The objective ancillary is public health care but that is an incidental aspect to the legislation.³¹ Also the courts assumption is always to the constitutionality of the legislation.³²

The entries to the legislative lists are not sources of the legislative power but are merely topics or fields of legislation and must receive a liberal construction inspired by a broad and generous spirit and not in a narrow pedantic sense.³³

Article 47 of the Constitution of India deals with the subject of duty of the State to raise the level of nutrition and the standard of living and to improve public health. The said Article is comprised under Part IV of the Constitution and Article 36 of the said Part IV clarifies that unless the context otherwise requires, "the State" has the same meaning as in Part III. Article 12 of Part III defines the term "State" as, unless the context otherwise requires, "the State" includes the Government and Parliament of India and the Government and the Legislature of each of the States and all local or other authorities within the territory of India or under the control of the Government of India.

The objective behind the enactment of the Tobacco Act is to discourage the advertisement and use of tobacco products by imposing certain restrictions in that regard. Ultimately, such measures may result in avoiding supply and distribution of such products to the minors and to that extent to bring about healthier lifestyle of the public at large. This was not a substantial encroachment as held by the court.³⁴

Prevention of Cruelty to animals Act a central legislations under List III, legislative competence was questioned vis-à-vis the Karnataka Municipal Corporation Act that dealt with stray dogs under List II. The court applied pith and substance and said that the legislation should be construed harmoniously and gave way to the Central Act.³⁵

Therefore construing the precedents set by various courts for pith and substance and analysing the facts of the case the respondents humbly submit that the present amendment act is competent.

³¹*State of Bihar & Ors.v.Shree Baidyanath Ayurved Bhawan Private Ltd. &Ors.* AIR 1996 SC 2829.

³²*Ashutosh Gupta v. State of Rajasthan*AIR 2002 SC 1533.

³³*Ujagar Prints etc v. Union of India & Ors* 1989 (3) S.C.C.488; *Welfare Association A.R.P., Maharashtra & Anr v. Ranjit P. Gohil & Ors.* Civil Appeal No 5168 of 1998.

³⁴*Sai Traders A Proprietary Concern v. State Of Goa & Ors* 2006(4) Bom.C.R.1.

³⁵*Master Jishnu G v. Bruhat Bangalore Mahanagara*W.P.No.37197/2011.

Also the question of a law under List I and a law under List II being in conflict would arise only when there exists a law that has the authority to grant compulsory license to reduce healthcare costs, which is not possible since compulsory license can only be provided by the Comptroller of Patents under the Patent Act.

Therefore there is not even a conflict of laws that the courts need to harmonize.

Whenever a legislature's authority is limited or restricted, the legality of its legislation can only be determined by a process of reasoning that involves "classifying" the impugned legislation according to the subject matter, and then seeing whether or not that subject matter falls within the area over which the legislature has authority. The contested act will be valid if it is made in "relation to" or "with respect to" a subject matter over which the legislature is competent.³⁶

³⁶Paul Craig & Mark Walter, *The Courts, Devolution And Judicial Review And The Constitution* 237 (Ed. 2000).

III. WHETHER THE ARTICLE 301 IS VIOLATED BY THE SAID AMENDMENT ACT 2012?

Article 301 provides for the freedom of inter State as well as Intra State trade, commerce and intercourse, subject of course, to the provisions of this part. The object of the freedom declared by this Article is to ensure that the unity of India may not be broken up by any internal barriers³⁷, or restrictions which directly and immediately affect the free flow of trade, commerce and intercourse.³⁸

Firstly the Appellants are not competent to file a petition under Article 301.

Article 19(1) (g) lays down the rights of the citizens in matter of profession , trade or business Article 301 deals with “how” the trade, commerce and intercourse are to be carried between one place and the other.

As far as non citizens are concerned, the right to carry on trade is not guaranteed and Article 301 cannot be used to create that right when Article 19 by its limiting words expressly limits that right to citizens.³⁹

Under the said petition the petitioners are claiming a right envisaged under Article 19(1)g under Article 301. This is because Article 19(1)g talks about trade, commerce and business at rest and 301 talks about the movement of trade, commerce and business.

What the petitioner are claiming is a violation of a right to trade and commerce at rest, which also is not being violated but even then, this contention does not stand.

Even rights under Article 19(1) (g) are not absolute, even though they are fundamental rights. Rights guaranteed under Article 19(1) (g) can also be restricted or curtailed in the interest of general public imposing reasonable restrictions on the exercise of rights conferred under Article 19(1)(g). Laws can be enacted so as to impose Regulations in the interest of public health, to prevent black marketing of essential commodities, fixing minimum wages and

³⁷*State of Bombay v. RMD Chamar Baughwala* AIR 1957 SC 699.

³⁸*State of Madras v. Nataraja* AIR 1969 SC 147.

³⁹H.M SEERVAI, CONSTITUTIONAL LAW OF INDIA 2592(4 ed. 2007).

various social security legislations etc., which all intended to achieve socio-economic justice.⁴⁰

Secondly, the said Amendment Act does not prohibit the petitioners from carrying on their trade or business. Nor is the Act restricting the petitioners from carrying the business. There has been no impedance in their trade that the legislation instigates.

The right under Article 301 is not absolute and is restricted. The permissive privilege to deal in liquor is not a “right”. It was held that freedom guaranteed by Article 301 is not available to liquor because it is a noxious substance injurious to public health, order and morality.⁴¹

In trades or businesses which are not in the interests of the general public, may be completely prohibited while others may be permitted with reasonable restrictions on them.⁴²

Therefore for public health, trade and business rights bestowed upon by Article 301 can be restricted. Article 302 and Article 304(b) enumerate that those restrictions that promote public health are valid.⁴³

Therefore the respondents contend that firstly the petitioners cannot take recourse of Article 301. Even if they do the right under Article 301 is not being violated. However even if the absolute right to carry on trade and commerce is being infringed the same is permissible for public health and in public interest under Article 302 and 304.

Merely because an alternative action could have served the purpose, the legislation cannot be struck down on this ground alone. A single institution is treated as a class by itself if there are special circumstances which are applicable to that institution Hence this legislation too cannot be struck down on such grounds.⁴⁴

⁴⁰*Society for Un-aided Private Schools of Rajasthan v. Union of India & Anr.* AIR 2012 SC3 445.

⁴¹*Southern Pharmaceuticals & Chemicals Ltd.v.State of Kerala* AIR 1981 SC 1863; *Muralidhar v. State of Rajasthan* AIR 2000 Raj 170.

⁴²*Khoday Distilleries Ltd. & Ors .v. State of Karnataka & Ors.*(1995) 1 SCC 574.

⁴³*State of Karnataka v.Hansa Corporation* AIR 1981 SC 463 ¶ 35.

⁴⁴*Dharam Dutt & Ors. v. Union of India & Ors.* AIR 2004 SC 1295.

IV. WHETHER THE AMENDMENT ACT SUFFERS FROM THE VICE OF EXCESSIVE DELEGATED LEGISLATION AND HENCE, IS UNCONSTITUTIONAL?

It is recognised on all hands that the modern complex socio economic problems cannot be met adequately without resorting to delegated legislation. Usually the courts lean in favour of the validity of the delegated legislation, and have upheld very broad delegated legislations.

In this case firstly there is no delegated legislation per se because it is conditional legislation.⁴⁵

The distinction between conditional legislation and delegated legislation is clear and unambiguous. In a conditional legislation the delegate has to apply the law to an area or to determine the time and manner of carrying it into effect or at such time, as it decides or to understand the rule of legislation, it would be a conditional legislation. The legislature in such a case makes the law, which is complete in all respects but the same is not brought into operation immediately. The enforcement of the law would depend upon the fulfilment of a condition and what is delegated to the executive is the authority to determine by exercising its own judgment as to whether such conditions have been fulfilled and/or the time has come when such legislation should be brought in force. The taking effect of a legislation, therefore, is made dependent upon the determination of such fact or condition by the executive organ of the Government. Delegated legislation, however, involves delegation of rule making power of legislation and authorises an executive authority to bring in force such an area by reason thereof.⁴⁶

In *State of Tamil Nadu v K. Sabanayagam*⁴⁷ excessive delegated legislation was contended for a Section that empowered the Government to exempt any establishment or class of establishment from the provisions having regard to the “financial and other relevant considerations”.

⁴⁵*Queen v. Burah* 5 IA 178 (1878); *In re Delhi Laws Act* AIR 1951 SC 332; *M.P High Court Bar Association v. Union of India* (2004) 11 SCC 766; *ITC Bhadrachalam Paper Boards v. M&al Revenue Officer* (1996) 6 SCC 634.

⁴⁶ *Vasu Dev Singh & Ors. v Union of India & Ors.*

⁴⁷ *The South Central Railway v. Registrar of Co-operative* AIR 1998 SC 334.

In the present case there is conditional legislation and not excessive delegated legislation because the Government has to apply the policy enshrined upon the Amendment act and not make rules for the same. However the discretion of the Government was to be applied it is conditional legislation under the concept of Administrative Law.⁴⁸

Therefore conditional legislation contains no element of delegation of legislative power and is, therefore, not open to attack on the ground of excessive delegated legislation.⁴⁹

⁴⁸*K.S.E. Board v. Indian Aluminium* AIR 1976 SC 1031.

⁴⁹*State of Tamil Nadu v. K. Sabanayagam* AIR 1998 SC 344; *Hamdard Dawakhana v. Union of India* AIR 1960 SC 554; *Union of India v. Cynamade India Ltd.* AIR 1987 SC 1802.

PRAYER

In the light of the authorities cited, questions presented and the arguments advanced, it is most respectfully prayed before this Hon'ble Court that it may be pleased to adjudge and declare that:

1. The petition be dismissed
2. The said Patent Amendment Act of 2012 is constitutionally valid.

Or pass any other order as it deems fit in the light of justice, equity and good conscience.

For which the respondents do and shall always pray

All of which is respectfully submitted on behalf of

The Respondent

Sd/-

Counsel for the Respondent