

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

---

---

**TABLE OF CONTENTS**

---

---

ABBREVIATIONS.....	2	
INDEX OF AUTHORITIES.....	4	
STATEMENT OF JURISDICTION.....	7	
STATEMENT OF FACTS.....	8	
QUESTIONS PRESENTED.....	10	
SUMMARY OF PLEADINGS.....	11	
PLEADINGS.....	13	
I.WHETHER PROVISIONS OF THE PATENT AMENDMENT ACT, 2012 ARE ARBITRARY AND DISCRIMINATORY, HENCE VIOLATIVE OF ARTICLE 14?		
A. The provision providing for grant of compulsory license of patented invention is violative of Article 14.....	13	
B. The provisions for grant of compulsory license of patented invention are arbitrary and unreasonable.....	18	
II.WHETHER THE AMENDMENT ACT VIOLATES THE SCHEME OF DISTRIBUTION OF POWERS BETWEEN THE CENTRE AND THE STATE AND THEREFORE IS UNCONSTITUTIONAL?.....		23
III. WHETHER THE SAID AMENDMENT VIOLATES THE PROVISIONS OF ARTICLE 301 OF THE CONSTITUTION OF GERM-MANY?.....		26
IV. WHETHER THE AMENDMENT ACT SUFFERS FROM THE VICE OF EXCESSIVE DELEGATED LEGISLATION AND HENCE, IS UNCONSTITUTIONAL?.....		29
PRAYER.....	31	

---

## ABBREVIATIONS

---

- & .....AND
- ¶ .....PARAGRAPH
- AIR.....ALL INDIA REPORTER
- Anr.....ANOTHER
- Art.....ARTICLE
- Assn.....ASSOCIATION
- Aug.....AUGUST
- Bom.C.R.....BOMBAY CASES REPORTER
- Ch.....CHANCERY DIVISION
- Co.....COMPANY
- Doesn't.....DOES NOT
- Ed.....EDITION
- EMR.....EXCLUSIVE MARKETING RIGHTS
- Govt.....GOVERNMENT
- Hon'ble.....HONOURABLE
- i.e.....THAT IS
- *Ibid*.....IBIDEM
- Inc.....INCORPORATION
- Ltd.....LIMITED
- MIPR.....MANUPATRA INTELLECTUAL PROPERTY REPORTS
- Ors.....OTHERS
- PARA.....PARAGRAPH
- Pg.....PAGE
- PTC.....PATENTS AND TRADEMARKS CASES
- RCR.....RECENT CRIMINAL REPORTS
- RCR.....RECENT CIVIL REPORTS
- Rly.....RAILWAY
- Rs.....RUPEES
- S/d.....SIGNED
- SC.....SUPREME COURT

- SCC.....SUPREME COURT CASES
- SCR.....SUPREME COURT RECORD
- Sec.....SECTION
- TRIPS...TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS
- U.S.....UNITED STATES
- v.....VERSUS
- WTO.....WORLD TRADE ORGANIZATION

---

## INDEX OF AUTHORITIES

---

### **ARTICLES REFERRED:**

- Deli Yang, Compulsory Licensing: For Better or For Worse, the Done Deal Lies in the Balance, 17 Journal of Intellectual Property Rights 76-81 (2012).
- Indian Kanoon, Lok Sabha Debates (2005), <http://www.indiankanoon.org/doc/215520/>(last accessed on Aug. 20, 2013).

### **BOOKS REFERRED:**

- DURGA DAS BASU, ADMINISTRATIVE LAW (6 ed. 2004).
- DURGA DAS BASU, COMMENTARY ON THE CONSTITUTION OF INDIA (8 ed. 2009).
- HM SEERVAI, CONSTITUTIONAL LAW OF INDIA (4ed. 2007).
- MP. JAIN & SN. JAIN, PRINCIPLES OF ADMINISTRATIVE LAW (6ed. 2007).
- MP. JAIN, INDIAN CONSTITUTIONAL LAW (6ed. 2007).

### **CASES REFERRED:**

- **FOREIGN CASE**
- *Canada-Patents case* WTO Panel on Canada - Patent Protection of Pharmaceutical Products, Report of the Panel on Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R.
- **INDIAN CASES**
- *Atiabari Tea Co. Ltd. v. State of Assam* AIR 1961 SC 232.
- *Bailey v. Drexel Furniture Co.* [1922] 250 US 20.
- *Commissioner of Central Excise Jamshedpur v. Dabur (India) Ltd.* (2005) 3 SCC 646.
- *Devidas Gopal Krishnan & Ors v. State of Punjab & Ors.* AIR 1967 SCR 557.
- *District Collector v. Ibrahim* AIR 1970 SC 1275.

- *District Registrar and Collector v. Canara Bank* AIR 2005 SC 186.
- *Federation of Rly. Officers Assn. v. Union of India* AIR 2003 SC 1344.
- *Gurcharan Singh v. Union Territory Chandigarh & Ors.* 2012(3) RCR (Civil) 387.
- *Harakchand v. Union of India* AIR 1970 SC 1453.
- *Hindustan Lever Ltd. v. Lalit Wadhwa* 2007 (35) PTC 377.
- *Jagdish Pandey v. Chancellor, Bihar University* AIR 1968 SC 353.
- *KCG Narayan Deo v. State of Orissa* AIR 1953 SC 375.
- *Kedar Nath v. State of West Bengal* AIR 1953 SC 835.
- *Khambalia Municipality v. Gujarat State* AIR 1967 SC 1048.
- *Laxmi Khandsari v. State of Uttar Pradesh* AIR 1981 SC 873.
- *M. Mohan Kumar v. P. Nalla Thampy Thera & Anr.* (2009) 8 SCC 46.
- *Madras v. Nataraj Mudaliar* AIR 1969 SC 147.
- *Makhan Singh v. State of Punjab* AIR 1979 SC 381.
- *Midas Hygiene Industries P. Ltd. v. Sudhir Bhatia & Ors.* 2004 (28) PTC 121 SC.
- *Naraindas v. State of Madhya Pradesh* AIR 1974 SC 1232.
- *Novartis AG v. Union of India* Civil Appeal Nos. 2706-2716 of 2013.
- *Proctor v. Bayley* 1889 (42) Ch 390.
- *Ram Jawaya Kapoor v. State of Punjab* AIR 1955 SC 549.
- *S.S. Bola v. B.D Sardana* AIR 1997 SC 3183.
- *Sai Traders A Proprietary Concern. v. State Of Goa And Ors.* 2006 (4) Bom.C.R. 1.
- *Satpal & Co. Etc v. Lt. Governor of Delhi And Ors.* 1979 SCR (3) 651.
- *Shri Meenakshi Mills Ltd. v. A.V. Visvanatha Sastri* AIR 1955 SC 13.
- *Sonapur Tea Co. v. Deputy Commissioner* AIR 1962 SC 137.
- *State of Bihar v. Kameshwar Singh* 1952 1 SCR 889.
- *State of Haryana v. Jai Singh* AIR 2003 SC 1696.
- *State of Maharashtra v. Indian Hotels & Restaurants Association* 2013(3) RCR (Criminal) 455.

**CONSTITUTION REFERRED:**

- The 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 32<sup>1</sup> of the Constitution of Germany.

---

<sup>1</sup>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 lifesaving 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 consider 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 interalia, arbitrary and discriminatory.

---

## QUESTIONS PRESENTED

---

I. Whether provisions of the Patent Amendment Act, 2012 are arbitrary and discriminatory, hence violative of Article 14?

A. The provision providing for grant of compulsory license of patented invention is violative of Article 14.

B. The provisions for grant of compulsory license of patented invention are arbitrary and unreasonable.

II. Whether the Amendment Act violates the scheme of distribution of powers between the Centre and the State and therefore is unconstitutional?

III. Whether the said Amendment violates the provisions of Article 301 of the Constitution of Germany?

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

---

## SUMMARY OF PLEADINGS

---

### **I. Whether provisions of the Patent Amendment Act, 2012 are arbitrary and discriminatory, hence violative of Article 14?**

The Petitioner humbly submits that the impugned legislation is violative of Article 14 of the Constitution. The classifications purported by section i (b), i.e. "not manufactured in the territory" and section ii, i.e. "pharmaceutical patent infringement suits" are unreasonable classifications as they have no reasonable or rational nexus with the object of the Patent Amendment Act, 2012 which is to reduce healthcare costs. Additionally, section i (a) and section iii provide for excessive discretion to the authority in absence of guidelines or principles. Hence, the amendment is violative of Article 14 and liable to be struck down.

### **II. Whether the Amendment Act violates the scheme of distribution of powers between the Centre and the State and therefore is unconstitutional?**

The Petitioner respectfully submits that the impugned legislation is liable to be struck on the grounds of want of legislative competence. The Legislature has no competence to legislate upon public health as it falls exclusively under State List, but under the guise of Intellectual property, the Legislature has purported to do so. Hence, it is colourable exercise of power which goes against the scheme of the Constitution.

### **III. Whether the said Amendment violates the provisions of Article 301 of the Constitution of Germany?**

The Petitioner humbly submits that the legislation while providing for compulsory licensing is violative of Article 301 of the Constitution. The right to freedom of trade, commerce and intercourse within the territory is being infringed upon as the generic versions of patented drugs are available at comparatively cheaper prices. Given the huge difference between the haves and have-nots in the country, the sale of the patented drug will reduce considerably hindering the trading activities of the Petitioners. Hence, the impugned legislation is liable to be quashed.

**IV. Whether the said amendment suffers from the vice of excessive delegated legislation and hence, is unconstitutional?**

The Petitioner respectfully submits that the impugned legislation provides for excessive delegated legislation and hence is contrary to the Constitutional scheme. The Government has unlimited power to determine what constitutes the following terms of wide amplitude: "national emergency", "extreme urgency" or "public non-commercial use." This power is vested in the authority devoid of any guidelines or principles for adherence. Hence, the legislation must be struck down as unconstitutional.

---

---

## PLEADINGS

---

---

### **I. Whether provisions of the Patent Amendment Act, 2012 are arbitrary and discriminatory, hence violative of Article 14?**

---

#### **A. The provision providing for grant of compulsory license of patented invention is violative of Article 14.**

The Petitioner humbly submits that the impugned act, i.e. the Patent Amendment Act, 2012 is violative of Article 14 of the Constitution.

#### **Object of the Patents Act, 1970 and its amendments**

‘Patent’ is not a dirty word. Patent is, in fact, intended to encourage inventions. At the same time, it is to strike a right balance between the financial and economic rights of the patentee and the welfare of the society. This is the endeavour of this Government – that this law strikes a right balance between patent holders’ rights and earnings and consumers’ interests, and economic development to ensure maximum social welfare of the people of the country, who should not be denied access to effective, safe and quality medicines.<sup>2</sup>

In the *Canada-Patents case*,<sup>3</sup> according to Germany, at issue was the question of balance in the TRIPS Agreement between exclusive rights conferred on the owner of a patent and recognized exceptions to those rights. Germany adopted the view that any tilting to the balance one way or the other would be a gross misinterpretation of the TRIPS Agreement and its objectives. This balance was of a fundamental, systemic importance for several countries including, in particular, developing countries.

---

<sup>2</sup>Indian Kanoon, Lok Sabha Debates (2005), <http://www.indiankanoon.org/doc/215520/>(last accessed on Aug. 20, 2013).

<sup>3</sup> WTO Panel on Canada - Patent Protection of Pharmaceutical Products, Report of the Panel on Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R at ¶ 7.94 (Aug. 27, 2013), <http://docsonline.wto.org/DDFDocuments/t/WT/DS/114R.DOC>.

***1. The classification purported in Section ii. whereby only pharmaceutical patent infringement suits are barred from availing interim injunction is unreasonable and has no nexus with the object of Amendment Act.***

In the present case, Section ii of the Patent Amendment Act, 2012 takes away the remedy of interim injunction from the patentee in a pharmaceutical patent infringement suit only which the Petitioner humbly submits is violative of Article 14 of the Constitution.

Article 14 forbids class legislation but permits reasonable classification which fulfils the following two tests:

- i. classification should be based on intelligible differentia and must be real and substantial; and
- ii. the differentia adopted must have a reasonable or rational nexus with the object of the act in question.<sup>4</sup>

In the present case, the classification has been made between pharmaceutical patents and non-pharmaceutical patent infringement suits. This classification holds no substantial or real value. The implication of this differentiation is that all the *litigants similarly situated* (i.e. patentees under the Patent Act, 1970) are not entitled to avail themselves of the same procedural rights for relief which goes against the spirit of Article 14. It is only permissible **if** the differentia is rational and has nexus to the object sought.<sup>5</sup> In the present case it is not fulfilled.

The Apex Court in a case<sup>6</sup> held that:

*“...in order to determine the reasons or justification for classification, the court may refer to relevant material, for example, objects and reasons appended to a Bill, parliamentary debates, matters of common knowledge, the background circumstances leading to the passage of the Act, etc.”*

The statement provided in the Factsheet preceding the highlights of the Amendment clearly portrays the object of the Legislature of Germany. It was to reduce healthcare-costs and provide affordable medicines to citizens.<sup>7</sup>

---

<sup>4</sup>*Laxmi Khandsari v. State of Uttar Pradesh* AIR 1981 SC 873; *State of Haryana v. Jai Singh* AIR 2003 SC 1696.

<sup>5</sup>*ShriMeenakshi Mills Ltd. v. A.V. VisvanathaSastri* AIR 1955 SC 13.

<sup>6</sup>*JagdishPandey v. Chancellor, Bihar University* AIR 1968 SC 353.

There exists no reasonable or rational nexus between the object of reducing healthcare costs and barring the interim injunction.

On the contrary, if *this provision is not struck down* it would act as an advocate for generic drug producers to make, sale or import patented drugs till a suit for infringement is filed by the patentee and the matter is decided in trial by the court.

On the other hand, if at the end of the trial, the matter is decided in favour of the patentee that the defendant indeed was an infringer, then the court would be left with no tool to nullify the acts of infringement conducted due to barring of the interim injunction remedy. It would indeed legalize the infringement for the time-period till the courts decided upon the same.

In order to determine whether the classification has nexus with the object, the court should first see that in the operation of the classification, whether the object sought is achieved.<sup>8</sup> In the present case, the object is not achieved. The object of reducing health care costs cannot be achieved by barring a remedy of interim injunction. Patents are granted under the current Act after scrutiny at various levels like before the Controller, pre-grant oppositions, post-grant oppositions,<sup>9</sup> appeal to Intellectual Property Appellate Board,<sup>10</sup> validity of patent challenged during an infringement suit,<sup>11</sup> etc. Hence, the presumption against the validity of the patent in unreasonable and frustration of the procedure laid down under the Patents Act, 1970 for grant of patent.

The Apex Court in a landmark case<sup>12</sup> held that:

*"...in cases of infringement, normally an injunction must follow..."*

Thus, if the patentee is successful in establishing a prima facie case, he must be allowed to avail an interim injunction<sup>13</sup> and the court can then decide upon the validity of the patent at the stage of trial.

In the present case, instead of reducing healthcare-costs, the barring of interim relief to the patentee will prejudice the rights of the patent-holders and promote infringement.

---

<sup>7</sup>Pg. 1 of the Factsheet, ¶ 5.

<sup>8</sup>*Kedar Nath v. State of West Bengal* AIR 1953 SC 835.

<sup>9</sup>The Patents Act, Section 25(2) (1970).

<sup>10</sup>The Patents Act, Section 117A (1970).

<sup>11</sup>The Patents Act, Section 107 (1970).

<sup>12</sup>*Midas Hygiene Industries P. Ltd. v. Sudhir Bhatia & Ors.* 2004 (28) PTC 121 SC.

<sup>13</sup>*Proctor v. Bayley* 1889 (42) Ch 390; *Hindustan Lever Ltd. v. Lalit Wadhwa* 2007 (35) PTC 377.

Hence, the provision is violative of Article 14 and liable to be declared unconstitutional.

***2. The grant of compulsory license to any applicant on the ground of "patented invention not manufactured in Germ-many" permits discrimination not permitted by Article 14.***

The Petitioner humbly submits that the grant of compulsory license on the ground of patented invention not worked in the territory of Germ-many is discriminatory in nature fulfilling no object intended by the Legislature. Hence, it is violative of Article 14.

Article 27 of TRIPS Agreement<sup>14</sup> states, in the pertinent part, that

*“...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.”*

In the case of *Canada - Patent Protection of Pharmaceutical Products*,<sup>15</sup> the WTO Panel also held the following:

*7.91...Article 27.1 prohibits discrimination as to enjoyment of "patent rights" without qualifying that term... The acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of Article 27.1, without the need for any textual provision so providing...*

In line with the above ruling, the Petitioner puts forth the interpretation that while granting of compulsory license, the Amendment Act cannot violate non-discrimination rules laid down in Article 27 of TRIPS Agreement.

Section i(b) of the Patent Amendment Act, 2012, which provides for a compulsory licence if the invention is not manufactured in India ('local working' provision), could also arguably

---

<sup>14</sup> Article 27, Trade Related Aspects Of Intellectual Property Rights 1996 (TRIPS).

<sup>15</sup> WTO Panel on Canada - Patent Protection of Pharmaceutical Products, Report of the Panel on Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R at ¶ 7.94 (Aug. 27, 2013), <http://docsonline.wto.org/DDFDocuments/t/WT/DS/114R.DOC>.

fall foul of Article 27 which, as mentioned above, prohibits any discriminatory treatment based on whether products are imported or locally produced.

The WTO Panel rejected the contention of Canada that Article 30 overrode the non-discrimination provision in Article 27.1, as this would necessarily lead to the result that exceptions could also be made as to the place of the invention or whether products were imported or locally produced. In other words, exceptions could be made if the place of invention was outside Canada, without making the same exception if the invention had been made in Canada. Equally, one could confine the exception to imported products and not apply it to locally produced products. Clearly, these consequences were not intended by the TRIPS negotiating parties.<sup>16</sup>

The Petitioner would humbly submit that a Parallel line of interpretation can be drawn in respect of Article 31 of the Agreement. If, in the application of this article, the above rule is not applied it would lead to arbitrary discrimination between the patentees who manufacture locally and those who import. This discrimination is violative of Article 27 of the TRIPS Agreement as well as Article 14 as well.

The purpose of granting compulsory license as enumerated in the TRIPS Agreement is to ensure supply of patented invention in the domestic market. The same is the purpose intended to be achieved by Section i (b) but the words it is clothed in permits unreasonable classification which will not fulfil the object of granting compulsory license.

Hence, the Government is bending the law to satisfy its personal requirements of making use of the knowledge of the patentee (in order to work the patented invention in the country) which goes against the philosophy of patenting.

Therefore it will be liable to be struck down.

---

<sup>16</sup>*Ibid.*

**B. The provisions for grant of compulsory license of patented invention are arbitrary and unreasonable.**

The Petitioner humbly submits that the present amendment act suffers from the vice of arbitrariness and unreasonability, hence violative of Article 14 of the Constitution.

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

The impugned provision providing for grant of compulsory license on grounds of "reasonable requirement of public" not met is couched with vast and unguided power, hence arbitrary and unreasonable.

The TRIPs Agreement specifically allows Member States to grant compulsory licenses on grounds to be determined by each Member country.<sup>17</sup> This unclear position was further clarified by the Doha Declaration of Ministerial conference held in November, 2001.

**Doha Declaration on TRIPS and Public Health: Sub-Paragraph 5 (b)**

*“5. Accordingly and in the light of Paragraph 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.”*

Compulsory licenses specifically related to medicines have been provided in other countries as well. For instance, French law authorizes compulsory licenses when medicines are “only available to the public in insufficient quantity or quality or at abnormally high prices”. In Israel, a license can be granted, if it is necessary to assure the public of a reasonable quantity of a product capable of being used as a medicament, to manufacture a medicament or a patented process for manufacturing a medicament (section 120(a)(1) and (2))<sup>18</sup>

---

<sup>17</sup> Article 31, Trade Related Aspects of Intellectual Property Rights 1996 (TRIPS).

<sup>18</sup> <http://apps.who.int/medicinedocs/fr/d/Jh2963e/14.1.html> (last accessed on 6th September 2013).

Reasonableness is a relative term which has to be interpreted differently on the basis of circumstances of each case. "Reasonable requirements of the public is a phrase of wide amplitude. Furthermore, "public" denoted different sections of the public comprising of the rich class, the middle-class and the poor class. Hence, the reasonable requirement of the public is highly subjective. It provide for a general heading capable of attracting innumerable situations which are not even intended to.

Under the impugned provision, vide plethora of situations can be included under the guise of reasonable requirements as the provision doesn't specifically enlist the reasonable requirements except one (affordability of prices by majority).

Even the ground of reasonable affordability of majority people suffers from arbitrariness. Reasonably affordable prices will not merely be dependent upon the purchasing power of the people. Nor does it relate to the lowest price relative to the cost of manufacturing alone. Moreover, it must necessarily take into account the cost of Research and Development and the reasonable gain of the patentee.

Hence, this action of the state is arbitrary and unreasonable as it is capable of being misused in situations not fit for grant of compulsory license in the absence of guidelines or policy in the legislation.<sup>19</sup>

The impugned provision wherein compulsory license can be granted to ensure affordability of drugs to the majority is uncalled for in the legislations of Germ-many.

In the recent Hon'ble Supreme Court case of *Novartis AG v. Union of India*,<sup>20</sup> the Appellant approached the Apex Court challenging the validity of an order passed by Intellectual Property Appellate Board rejecting the grant of patent to the appellant.

The Board rejected the patent application on two specific grounds namely;

- a) the application doesn't satisfy the requirements laid down by the Act under Section 3(d) and

---

<sup>19</sup>*Commissioner of Central Excise Jamshedpur v. Dabur (India) Ltd.* (2005) 3 SCC 646; *Federation of Rly. Officers Assn. v. Union of India* AIR 2003 SC 1344.

<sup>20</sup>Civil Appeal Nos. 2706-2716 of 2013.

- b) Section 3(b) of the Act was being violated as the grant of patent would cause exploitation leading to public disorder among other things. (this provision is in consonance with Article 27.2 of the TRIPS Agreement)

The Supreme Court upheld the following observations of the Appellate Board rejecting the patent application of **Novartis** for the drug:

*“When the Appellant was holding the right as EMR (Exclusive Marketing Rights) on GLEEVEC it used to charge Rs.1,20,000/- per month for a required dose of the drug from a cancer patient, which is too unaffordable to the poor cancer patients in India. Thus, a grant of product patent on this application can create a havoc to the lives of poor people and their families affected with the cancer for which this drug is effective. This will have disastrous effect on the society as well.”*

With the help of the above example, the Petitioner humbly submits that the existing provisions under the Patent Act, 1970 are sufficient enough to cater to the situations purported to be covered under the impugned Amendment Act. The above case is a classic precedent setting example of the exercise of such power possessed by these relevant provisions of the Act in order to make drugs available to the public at affordable prices.

Hence, the provision i (a) of the Patent Amendment Act, 2012 is unwarranted for.

Non-compliance with Article 31 of TRIPS Agreement:<sup>21</sup> Compulsory license should be granted on the basis of individual merit. [Art. 31(a)]

If, like in the present case, a class is created i.e. "reasonable requirement of public" the above requisite would be violated. The creation of such class would be supportive of patent infringement practices as it would provide for grant of compulsory license as a norm rather than an exception as intended under the TRIPS Agreement.

---

<sup>21</sup> 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:

(a) authorization of such use shall be considered on its individual merits;

**2) *The power with the Government to issue notification for automatic grant of compulsory license amounts to excessive discretion which is capable of violating the object of the Amendment Act.***

The Petitioners humbly submit that the impugned section iii of the amendment act provides for excessive discretion to the Government without any guidelines or procedure laid down. Hence, it is arbitrary and unreasonable.

Under this impugned provision, the Government call issue notification for automatic grant of compulsory license in three situations, namely:

- i. national emergency, or
- ii. extreme urgency, or
- iii. public non-commercial use<sup>22</sup>

None of these three situations have been elucidated upon in the impugned provision or the Amendment Act, 2012.

'National emergency' and 'public non-commercial use' are terms that leave a large room for interpretation. Basically, 'public non-commercial use' is a superfluous, open-ended term with no internationally standardized definition. Any country can exercise its power to declare a non-commercial government use of a patent that is not necessarily a national emergency or urgency (e.g. case in Thailand), but in national interest (e.g. defence). For example, the Thai government subsequently issued four more compulsory licenses in 2008 on the ground of public non-commercial use.<sup>23</sup>

Thus, who will decide that there is a national emergency? Who will decide that there is an extreme urgency?<sup>24</sup> Who will decide that it is required by public for a non-commercial use? It is the Government alone.

The Amendment Act lays down no principles or guidelines guiding the Government for the exercise of this discretion. Though the Doha Declaration on TRIPS and Public Health, 2001

---

<sup>22</sup> Pg. 2 of the Factsheet, Highlight of the Patent Amendment Act, 2012 (iii).

<sup>23</sup> Deli Yang, Compulsory Licensing: For Better or For Worse, the Done Deal Lies in the Balance, 17 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS 76-81 (2012).

<sup>24</sup> Indian Kanoon, Lok Sabha Debates ( 2005), <http://www.indiankanoon.org/doc/215520/>(last accessed on Aug. 20, 2013).

tried to clarify the ground of national emergency till some extent but it also doesn't provide for any principles or guidelines.<sup>25</sup>

Hence, this is a clear case of absolute discretion in the hands of the Central Government capable of being misused or used arbitrarily.<sup>26</sup>

The Petitioner humbly submits an example of such arbitrary use of power by the Government. In the present case, the Government issued notification under this provision pertaining to all patented cancer drugs.<sup>27</sup> The current state of affairs in Germany fall under no category of national emergency or extreme urgency. Hence, the use of power under this provision was not required.

Hence, the provision is violative of Article 14 of the Constitution.

---

<sup>25</sup> ¶ 5 : Accordingly and in the light of Paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(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.

<sup>26</sup> *Naraindas v. State of Madhya Pradesh* AIR 1974 SC 1232; *District Registrar and Collector v. Canara Bank* AIR 2005 SC 186.

<sup>27</sup> Pg. 3 of the Factsheet, ¶ 3.

---

## **II. Whether the Amendment Act violates the scheme of distribution of powers between the Centre and the State and therefore is unconstitutional?**

---

The pivotal point of a federal constitution is the division of powers and functions between the Centre and the regions. The Indian Constitution contains a very elaborate scheme of distribution of powers and functions between the Centre and the States.

Under Article 246(3), powers are exclusively conferred to make laws with respect to matters enumerated in State List and represents the prohibited field for centre.

In the present case the centre does not have the legislative competence to pass the said Amendment Act of 2012. This is because the said piece of legislation is a colourable legislation.

The idea of colourable legislation is that the legislature purports to act within the limits of its power, yet in substance and reality, it has transgressed these limits of its power by taking resort to a mere pretence or disguise. If that is so the legislation in question is invalid.<sup>28</sup>

In the present situation the law that has been amended has been done so in the Patent Act 1970. This is because the legislature claims competence to the said amendment under Entry 49 of List I, but what it actually is doing is, making an amendment for public health that is a subject matter under Entry 6 of List II of the Schedule VII.

The courts have devolved a two tier test to determine the substance of the enactment; (a) effect of the legislation<sup>29</sup> and (b) object or purpose of the Act.<sup>30</sup>

In the facts it has been clearly mentioned that “pursuant to the policy to reduce healthcare cost” the said amendment was introduced. In the guise of amendment of Patent Act, the legislature in real and substance wants to make an amendment for public health and in pursuance of the same has carried out this amendment.

The clauses enshrined in the amendment also indicate clearly that the purpose of the Act that is the real intention of the Amendment Act was not in consonance with the Scheme of the Patent Act of 1970, but purported directly at making laws on and for public health.

---

<sup>28</sup>*S.S Bola v. B.D Sardana* AIR 1997 SC 3183.

<sup>29</sup>*KCG Narayan Deo v. State of Orissa* AIR 1953 SC 375.

<sup>30</sup>*Sonapur Tea Co v. Deputy Commissioner* AIR 1962 SC 137.

The real purpose of a legislation maybe different from what appears from its face, but it would be colourable legislation if the real object is not attainable by the legislature because it lies beyond its ambit.<sup>31</sup>

In the first case of colourable legislation that is *Bailey v. Drexel Furniture Co*<sup>32</sup> the power of Taxation vested with the Union and the Law made was for Child Labour Tax Law 1919. The US Supreme Court struck down the law based on colourable legislation as the Union did not have the power to regulate child labour and it could not do so indirectly by using its power of taxation. The same was upheld in the case of *State of Bihar v. Kameshwar Singh*.<sup>33</sup>

Public Health has been time and again been interpreted by the courts. Public health is a state matter and the ambit of the same was discussed by the Courts in *Sai Traders A Proprietary Concern. v. State Of Goa And Ors.*<sup>34</sup> where the court held that :

*“...even if the control of the tobacco industry is, by law made by Parliament, taken over by the Union Government, the State is not denuded of its powers to enact a law in respect of that industry in exercise of its powers with reference to different entry in the State List that is entry 6 of list II in this case.”*

Also in *Satpal & Co. Etc. v. Lt. Governor Of Delhi And Ors.*<sup>35</sup> it was upheld that:

*“Liquor traffic is a source of pauperism and crime. Such an impost, therefore, is one in the public interest for preserving public health and public moral and is not one as infringing the interstate freedom of trade and commerce. And the state has the right to make laws for the same.”*

If liquor is regarded as a matter of public health due to the after effects of consumption of the same then availability and consumption of medicines and drugs is definitely a matter of public health.

Therefore the petitioners humbly submit that the legislature is blatantly amending the Patent Act, but the purpose is not in consonance with the Scheme of the Act, as it says the object was to “blunt the patent blade”. Also the need to encroach upon the States matter was in evident. When such an encroachment is incidental it is permitted and has been. For example,

---

<sup>31</sup>*KCG Narayan Deo v State of Orissa* AIR 1953 SC 375.

<sup>32</sup>[1922] 250 US 20.

<sup>33</sup>1952 1 SCR 889.

<sup>34</sup>2006 (4) Bom.C.R.1.

<sup>35</sup>1979 SCR (3) 651.

a few sections of the Patent Act do deal with public health but the purpose of the Act was not the same. However the purpose of the Amending Act is public health and it is a real and substantive encroachment, which was not a sine qua non.

Hence, the said amendment is a piece of colourable legislation which should be struck down due to incompetence of the legislature to make the said legislation.

---

### III. Whether the said Amendment violates the provisions of Article 301 of the Constitution of Germ-many?

---

Free flow of trade, commerce and intercourse within a federal country is a pre-requisite for promoting economic utility of the country. According to Article 301 of the constitution of Germ-many, “trade, commerce and intercourse throughout the territory of Germ-many shall be free.”

Drawing attention to the importance of Art. 301, the Hon’ble Supreme Court has observed in that Art. 301:

*“...is not a declaration of mere platitude, or the expression of a pious hope of a declaratory character, it is also not a mere Statement of Directive Principle of State Policy, it embodies and enshrines a principle of Paramount importance that economic unity of the country will provide the main sustaining force for the stability and progress of the political and cultural unity of the country... emphasis added”<sup>36</sup>*

In the present dispute, the State of Germ-many issued a notification stating that all patented cancer drugs would automatically be subject to a compulsory license, and any such patent can be worked upon by private parties (who apply to the government for permission to use the patent) or the government itself or for public non-commercial use. It is the humbly submitted that such a notification is invalid, arbitrary and discriminatory. The impugned notification puts a direct and immediate restriction on the right of Medimax to carry on trade within the territory of Germ-many.

Grant of a compulsory license for the generic drug Placid to Medirip would directly and immediately hamper and restrict the trading activities of Medimax within the State of Germ-many. Medirip had already been selling the drug within the territory of Germ-many illegally and had clenched a share of the market, which would increase significantly subsequent to the grant of the said compulsory license. Further, the Patents Amendment Act 2012 mandates that law suits involving allegations of pharmaceutical patent infringement shall dispense off with the interim injunction phase and the matter should proceed directly to trial. This clearly implies that the production of Placid would continue even when the dispute is under trial and the grant of compulsory license would affect the trading activities of Medimax immediately.

---

<sup>36</sup>*Atiabari Tea Co. Ltd. v. State of Assam* AIR 1961 SC 232.

It is common knowledge the generic version of a drug is cheaper than the imported version (mostly due to no funds being spent on R&D by the generic drug manufacturing pharmaceutical company) and in a country like Germany where there is a huge difference between the haves and have-nots, the sales of 'Candid' will reduce by a considerable amount.

This reduction would hinder the trading activities of Medimax directly. The Hon'ble SC in *Madras v. Nataraj Mudaliar*<sup>37</sup> said "all restrictions which directly and immediately affect the movement of trade are declared by Art. 301 to be ineffective."

Such an action by the Govt. of Germany would also hamper the trade ties between the two countries. It might even lead to a reduction in foreign investment. The main objective of the act is to promote public good. However, the amendment would discourage Medimax which is a pharmaceutical conglomerate, from pursuing research on the multitude of maladies from which the citizens of Germany suffer.

In *District collector v. Ibrahim*<sup>38</sup>, the SC had invalidated an attempt by the state govt. to create a monopoly to deal in sugar in favour of co-operative societies. In the present case also, the notification issued by the govt. clearly tries to establish a market only for the Indian companies. Such an action taken by the govt. should be held invalid.

The govt. of Germany fails to appreciate the presence of various alternatives available within the parent act.

The state action prohibits Medimax to exercise its rights of a patent holder by granting compulsory license to Medirip. Such a situation could have been avoided if the govt. had harmoniously construed the provisions or alternatives already present in the patent act. The drafters of Act had already by way of the following Sections gave various alternatives:

Section 46 of Patent act, 1970 provides that a patent under the Act would only be granted subject to the condition that if the patented invention is a drug or a medicine, then the Government reserves the right to import the drug or medicine for its own use or for public health distribution.

---

<sup>37</sup> AIR 1969 SC 147.

<sup>38</sup> AIR 1970 SC 1275.

Also, Section 66 of the Patent Act 1970 mentions that if the Govt. believes that the patentee holder is being mischievous or prejudicial to the public then the patent can be revoked after giving an opportunity of hearing to the patent holder.

Section 102 of the Patent Act 1970 talks of acquisition of invention and patent for public purpose which empowers the Government to acquire a patent to meet national requirements.

The above stated three points already give a cure for the problem, which means there was no need to issue the whole amendment.

SC recently delivered its verdict in the *Mumbai Bar dancers*<sup>39</sup> case in which it was stated that:

*“...the restrictions in the nature of prohibition cannot be said to be reasonable, in as much there could be several lesser alternatives available which would have been adequate to ensure public morality...emphasis added”*

---

<sup>39</sup>*State of Maharashtra v. Indian Hotels and Restaurants Association &Othrs* 2013(3) RCR(Criminal) 455.

---

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

---

There is a clear separation of power provided in the Constitution and under Article 245 the right to legislate vests with the Legislature. Delegated Legislation is unconstitutional in nature if it is excessive in nature.

The present case is overshadowed by excessive delegated legislation because the legislature has not laid down the policy in clear and unambiguous terms.<sup>40</sup> It is couched in vague and extremely wide terms.<sup>41</sup>

Power to legislate carries with it the power to delegate. But excessive delegation may amount to abdication. Delegation unlimited may invite despotism uninhibited. So the theory has been evolved that the legislature cannot delegate its essential legislative function. Legislate it must, by laying down policy and principle and delegate it may to fill in detail and carry out policy.<sup>42</sup>

In the present case Patents Amendment Act 2012 reinstated that the Government can issue a notification at any time calling for a compulsory license over a patented invention on the grounds of national emergency or extreme urgency or public non-commercial use. When Medirip after infringing the rights of petitioners, filed for a compulsory licensing, the same was granted to them on the grounds of a notification issued by the govt. the notification stated that all patented cancer drugs would automatically be subject to a 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.

Such a notification would be considered as vague, undefined and without any guidelines since the act fails to define public non-commercial use or a situation of extreme urgency or national emergency.<sup>43</sup>

---

<sup>40</sup>*Makhan Singh v. State of Punjab* AIR 1979 SC 381.

<sup>41</sup>*Khambalia Municipality v. Gujarat State* AIR 1967 SC 1048; *Harakchand v Union of India* AIR 1970 SC 1453.

<sup>42</sup>AIR 1980 (1) SCC 340.

<sup>43</sup>*Devidas Gopal Krishnan & Ors v. State of Punjab & Ors.* AIR 1967 SCR 557.

Hon'ble SC in the case of *Gurcharan Singh v. Union Territory Chandigarh & Ors*<sup>44</sup> had observed: “*Since the provisions of Section 7 are vague, undefined and without any guidelines, therefore, Section 7 suffers from the vice of illegality.*”

Also, in the case of *Ram Jawaya Kapoor v. State of Punjab*,<sup>45</sup> specific legislation may indeed be necessary when it is necessary to encroach upon private rights in order to enable the Government to carry on their business, sanctioning such course would have to be passed.

The TRIPS Agreement<sup>46</sup> read with the DOHA Declaration<sup>47</sup> have made an attempt to make the terminology as stated in the sections with respect to national emergency clear. But no such attempt has been made by the legislature and this legislative function has been excessively delegated to the executive.

---

<sup>44</sup>2012(3) RCR (Civil) 387.

<sup>45</sup>AIR 1955 SC 549.

<sup>46</sup>Article 31, Trade Related Aspects Of Intellectual Property Rights (1996).

<sup>47</sup>¶ 5(c), Doha Declaration on the TRIPS Agreement and Public Health (2001).

-----  
**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 allowed.
2. The said Patent Amendment Act of 2012 is unconstitutional as being violative of Fundamental Rights protected under Article 14.
3. The said Patent Amendment Act, 2012 is beyond the legislative competence of the Legislature.
4. The said Patent Amendment Act, 2012 is violative of Article 301 and compensation worth 44 lac rupees be paid to petitioners for loss in profits in Business and Trade.
5. The respondents be ordered to bear the cost of litigation.

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

**All of which is respectfully submitted on behalf of**

**The Petitioner**

Sd/

Counsel for the Petitioner