

21st October 2014

To,
The Secretary,
Department of Industrial Policy and Promotion
Ministry of Commerce and Industry
Udyog Bhawan, New Delhi

SUBJECT: REPRESENTATION UNDER SECTIONS 66 AND 92 OF THE PATENTS ACT, 1970 ON BEHALF OF CIPLA LIMITED, SEEKING REVOCATION OF INDIAN PATENT NOS. IN222346, IN230049, IN210047, IN230312 AND IN214320 REGISTERED IN FAVOUR OF NOVARTIS AG

Respected Sir,

We represent Cipla Limited, an Indian pharmaceutical company, having its registered office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai – 400 013. The present representation is being made invoking Sections 66 and 92 of the Patents Act, 1970 (hereinafter referred to as the 'Act') on behalf of Cipla Limited (hereinafter referred to as 'Cipla') seeking revocation of the following registered patents of Novartis AG (hereinafter referred to as 'Novartis'):

- a) **IN222346** titled "Beta 2 Adrenoceptor Agonists"
- b) **IN230049** titled "a process for the preparation of 5-(haloacetyl)-8-(substituted oxy)-(1h)-quinolin-2-ones"
- c) **IN210047** titled "Process for preparing 2-Aminoindan Derivatives"

- d) **IN230312** titled "A process for preparing 5-[(r)-2-(5,6-diethyl-indan-2-ylamino)-1-hydroxy-ethyl]-8-hydroxy-(1h)-quinolin-2-one salts"
- e) **IN214320** titled "A Pharmaceutical Composition Composition For The Treatment Of Inflammatory And Obstructive Airways Diseases"

The above-said patents pertain to products and processes of a drug whose International Non-proprietary Name (INN) is 'Indacaterol', having the molecular formula (R)-5-[2-[(5,6-Diethyl-2,3-dihydro-1H-inden-2-yl)amino]-1-hydroxyethyl]-8-hydroxyquinolin-2(1H)-one. The Complete Specifications of these patents are annexed herewith as **ANNEXURE A (Colly)**.

BRIEF SUMMARY OF THE PRESENT REPRESENTATION

1. The present representation is being filed under Sections 66 and 92 of the Patents Act, 1970, to bring to the notice of the Secretary, Department of Industrial Policy and Promotion, the gross misuse in the exercise of exclusive rights granted to Novartis with respect to the above-mentioned patents for the drug Indacaterol. The said drug is one of the preferred medications for a widely prevalent respiratory disease known as Chronic Obstructive Pulmonary Disease (hereinafter referred to as 'COPD'), with which about 1.5 crore patients in India are afflicted. COPD is a chronic lung ailment that is characterized by a persistent blockage of airflow from the lungs thereby resulting in difficulty in breathing, and could be fatal if untreated or incorrectly diagnosed.
2. It is the fundamental right of a citizen of India to live and that right to live includes a right to better healthcare. The 'Right to Life' includes in its purview the Right to healthcare as also

availability/affordable medicines. It is pertinent to note that the said drug is not being made available to the public at large, due to the fact that Novartis has failed to manufacture the said drug in India, by itself or through any of its licensees or make it available on a commercial scale in India. Only very insignificant amounts of the drug are being imported in India by Novartis through its alleged licensee Lupin Limited. Further, even the alleged imports are grossly inadequate, and do not, in any manner whatsoever, fulfil the requirements of the patient population in India. As calculated and demonstrated below, on the basis of the data furnished by Novartis to the Indian Patent Office, the shortage in the availability of the drug is to the extent of 99.97%. In fact, the disease is now prevalent to such an extent that it is being classified as an epidemic. Though there are other alternative treatment options available, the same are not adequate to deal with and respond to the growing scale of the advance of COPD. Moreover, the said alternative treatments also have their disadvantages in terms of dosage, efficacy etc.

3. Therefore, the present representation is being made to bring to the notice of the Department of Industrial Policy and Promotion the incorrect exercise of patent monopoly which is prejudicial to public interest and the mischief to the State resultant therefrom. Further, such non-availability of a drug is not only prejudicial to the State, but also severely impinges upon the citizens' Fundamental Right to access medicines in adequate quantities and at reasonable prices. The Fundamental right of the citizens of India under Article 21 is to include right to a better healthcare and adequate access to medicines and treatments. Therefore, by way of the present representation, it is prayed that the abovementioned patents, being IN222346, IN230049,

IN210047, IN230312 and IN214320 registered in favour of Novartis, be revoked by the Central Government in exercise of its statutory powers under Section 66 read with Section 92 of the Act.

4. The mischief of Novartis is further evidenced by the fact that there are a total of five patents applied for and granted – each of which claim to deal with and pertain to Indacaterol. None of the patents, including the process patents, are being worked in India. Therefore, the inescapable conclusion is that the purpose of filing multiple patents appears to be to enjoy extended monopoly and to restrict the availability of the drug. Thus, the continuation of the said patent rights is prejudicial to public interest.

INTRODUCTION

5. The Law in India places an obligation upon every patentee to exercise its patent rights in a manner which makes the products accessible and affordable. Patentees are required to place before the Patent Office details showing the working of a patent. The incorrect and abusive methods of enjoyment of patent rights are scorned under the statute and by way of said statute the power vests in the Central Government to revoke the patents.
6. By way of this representation, Cipla is endeavoring to bring to the notice of the Department of Industrial Policy and Promotion, Ministry of Commerce and Industry certain facts and circumstances with respect to the activities of Novartis, being the misuse of the exclusive rights inter alia, in the following manner:

- a. By not manufacturing the drug in India since the grant of the patent i.e., since 2008, either by itself or through any other Indian company;
 - b. By not transferring the technology for manufacture to any Indian company;
 - c. By only importing limited quantities of the drug through an Indian company by way of an alleged license which appears to be a complete `eyewash'; and
 - d. By not making available to the public, adequate quantities of the drug at reasonable prices for the patients in India for a disease which is prevalent in epidemic proportions.
7. Further, such conduct is detrimental to the public at large and is mischievous use of patent rights. It severely compromises the Fundamental Right of the citizens of India to have access to the medicine. Though the said patents are registered in India, and are owned by Novartis, the said patents have not been worked in India and there has been no Transfer of Technology, which in fact, is the ultimate aim/purpose with which patent protection and exclusive rights are granted. As a result of the said non-working of the abovementioned patents, the public at large has been denied access to a drug for curing and managing COPD.
8. The provision of law contained in Section 66 of the Patents Act, 1970, is reproduced hereinbelow for ease of reference:
- "66. **Revocation of patent in public interest:** Where the Central Government is of the opinion that a patent or the mode in which it is exercised is mischievous to the State of generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official*

Gazette and thereupon the patent shall be deemed to be revoked."

It is pertinent to note that Section 66 has been invoked on some occasions earlier, such as in the case of a process patent granted to Agracetus, an American company for genetically engineered cotton cell lines. The said patent was revoked by the Central Government in the year 1994 keeping in mind public interest and the fact that genetically engineered cotton, being a product of concern for the national economy, particularly for agriculturists, ought not to be the subject matter of a patent monopoly. Similarly, a patent granted to Avesthagan Limited for a "synergistic ayurvedic/ functional food bioactive composition" i.e. the composition consisting of Jamun, Lavangpatti and Chandan to be used for treatment of Diabetes. In light of the public interest in using traditional knowledge for curing and treating Diabetes, the said patent was also revoked under Section 66 of the Act.

9. Section 92 is set out hereinbelow for ease of reference:

"92. *Special provision for compulsory licences on notifications by Central Government*

(1) If the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licenses should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and thereupon the following provisions shall have effect, that is to say—

(i) the Controller shall on application made at any time after the notification by any person interested, grant to the applicant a licence under the patent on such terms and conditions as he thinks fit;

(ii) in settling the terms and conditions of a licence granted under this section, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

(2) The provisions of sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licences under this section as they apply in relation to the grant of licences under section 84.

(3) Notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section (1) that it is necessary in—

(i) a circumstance of national emergency; or

(ii) a circumstance of extreme urgency; or

(iii) a case of public non-commercial use,

which may arise or is required, as the case may be, including public health crises, relating to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of licence under this section:

Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87."

(emphasis added)

10. Cipla believes that COPD is one of the major causes of fatalities in India and therefore, proper treatment is essential. COPD has,

in recent years, assumed epidemic proportions as it is prevalent in people residing in urban, semi-urban and rural areas. The causes of COPD are several and the sheer magnitude of the disease as per the publicly available data is sufficient for the Central Government to invoke the provisions of Section 92 and to treat it as an “epidemic” or a “public health crisis”. Such exercise of power in the present case would be in consonance with the avowed purpose for which Section 92 has been enacted.

A. BRIEF PROFILE OF CIPLA LIMITED

- A.1 Cipla is presently one of India's largest pharmaceutical companies. In the year 1935, the Chemical, Industrial & Pharmaceutical Laboratories (which came to be popularly known as CIPLA) was set up by Khwaja Abdul Hamied. On 17th August 1935, Cipla was registered as a Public Limited Company. At the helm of affairs in Cipla is Dr. Y.K. Hamied, who is among India’s leading scientists, and was also awarded the Padma Bhushan Award in the year 2005.
- A.2 In the year 1952, a research division was set up by Cipla with the view of attaining self-sufficiency in technological development, and since then Cipla has been progressing firmly and steadily in the fields of pharmaceuticals and drug development. At present, Cipla has 34 world-class manufacturing facilities spread across the country, with dedicated plants for oncology products, hormones, inhalers, carbapenems, and cephalosporin, among others. The various manufacturing facilities of Cipla have been approved by several regulatory authorities (both national and international) including, *inter alia*, the following:

- Food and Drug Administration (FDA), USA;
- World Health Organisation (WHO);
- Medicines and Healthcare products Regulatory Agency (MHRA), UK;
- Therapeutic Goods Administration (TGA), Australia;
- Medicines Control Council (MCC), South Africa;
- National Institute of Pharmacy (NIP), Hungary;
- Pharmaceutical Inspection Convention (PIC), Germany;
- Department of Health, Canada;
- State Institute for the Control of Drugs, Slovak Republic;
- ANVISA, Brazil;
- SUKL-Slovak Republic;
- Danish Medical Agency;
- INVIMA- Colombia;
- NDA-Uganda; and
- MOH-Saudi Arabia

A.3 Cipla's Active Pharmaceutical Ingredient (API) manufacturing plants are amongst the most sophisticated plants in the world, capable of complex multi-stage syntheses producing over 120 APIs from high potency actives in grams to those made in several tonnes. Cipla produces one of the widest ranges of products and dosage forms in the world today including metered-dose inhalers, pre-filled syringes, trans-dermal spray patches, lyophilized injections, nasal sprays, medical devices, and thermolabile foams. Currently, Cipla's products are marketed in over 170 countries across the globe. Cipla invests about Rs. 521 Crores on R&D annually which is about 5.4% of its annual turnover.

A.4 Further, the following awards and recognitions have also been given to Cipla in recent times in view of its efforts:

- Dr. Y K Hamied, Chairman honoured with Padma Bhushan Award, 2005
- Pharma Excellence Award for sustained growth, 2005
- Dun and Bradstreet American Express Corporate Award, 2006
- Silver Plate Award by Help Age India, 2006
- Scrip Award for Best Company in an Emerging Market, 2006
- International Trade Award for outstanding exporter of the year in Pharmaceutical Category, 2006
- Listed in Forbes Asia's "Best under A Billion", 2007
- Dr. Y K Hamied recognized as the "Conscious Capitalist" at Forbes India Leadership Awards, 2012
- Received the "Outstanding Export Performance" Award in the export of Pharmaceuticals, 2011-12
- Dr. Y K Hamied honoured with the CNN-IBN Indian of the Year Award, 2012 in the Business Category
- Business Standard honoured Dr. Y K Hamied with the Lifetime Achievement Award at the Annual Awards, 2012
- Managing Intellectual Property declared Novartis AG v Union of India (which was defended by Cipla) as the "Case of the Year", 2013.
- CSR Best Practices award at ABP's Global CSR Excellence & Leadership Awards, 2014
- Ernst & Young awarded Dr. Y K Hamied with Lifetime Achievement Award, 2014
- Excellence Award in Environment Health & Safety (EHS) – 2013 to Cipla Virgonagar unit, Bangalore for practicing EHS policies from Confederation of Indian Industries (CII) Southern Region

- LegalEra award for the Best Pharmaceutical in-house Legal team at LegalEra awards, 2013-14.
- Environment Risk Management Company of the year award at 'India Risk Manager Awards 2013'.
- Network 18 and Infosys awarded Cipla for its innovation on HIV/AIDS drugs
- Cipla received the 'Silver' award from Pharmexcil for its Outstanding Performance in the export of Pharmaceuticals during the year 2012-13.

B. BRIEF PROFILE OF CIPLA IN MANUFACTURING MEDICINES FOR RESPIRATORY DISEASES

B.1 Cipla has a very strong presence in the area of respiratory products and has from time to time introduced various products for COPD, Asthma, Allergic Rhinitis (AR), Pulmonary Arterial Hypertension (PAH), lung cancer and Idiopathic Pulmonary Fibrosis (IPF) etc. The introduction of Salbutamol tablets in 1976 and Salbutamol inhaler in 1978 in India by Cipla was one of the path breaking steps taken by Cipla to ensure that the drugs be made easily available to patients, as also to further the interest of public health.

B.2 Further, other strides made by Cipla in the field of manufacturing and selling medicines for respiratory diseases include the launch of several respiratory products in the Indian market since 1972. Below is the list of products:

S No	Product	Launch year
1.	Asthalin [®] [Salbutamol]	1976
2.	Beclate [®]	1984

	[Beclomethasone]	
3.	Aerocort [®] [Beclomethasone + Salbutamol]	1990
4.	Foracort [®] [budesonide and Formoterol]	2001
5.	Foratec [®] [Formoterol]	2000
6.	Seroflo [®] [Fluticasone + Salmeterol]	2000
7.	Tiova [®] [Tiotropium]	2003
8.	Triohale [®] [Tiotropium + Formoterol + Ciclesonide]	2008
9.	Maxiflo [®] [Fluticasone + Formoterol]	2009

B.3 Moreover, it is pertinent to note that Cipla invests approximately Rs. 84 Crore annually, for the Research and Development of products/ medicines to cure/manage respiratory diseases, in view of its social consciousness towards the growing burden placed not only on patients and their families, but also on the national economy as a result of the widespread prevalence of respiratory diseases in India.

C. BRIEF INTRODUCTION TO CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

C.1 COPD is a chronic lung ailment that is characterized by a persistent blockage of airflow from the lungs thereby resulting in difficulty in breathing. It is an illness characterized by air flow limitation that is not fully reversible. COPD is usually progressive and is associated with pathological changes in the lung - a combination, varying between individual patients, of obstructive bronchiolitis and parenchymal destruction (emphysema). The principal environmental risk factor for the development of COPD is exposure to tobacco smoke, but occupational hazards or other

exposure to some chemicals and both organic and inorganic dusts e.g exposure to biomass fuel are also known to increase the risk. In India, an important risk factor for COPD is exposure to biomass smoke. This is commonly seen in rural areas where burning of twigs, leaves, wood, cow dung, etc is used for cooking and heating purposes. In fact exposure to biomass fuel could be a bigger threat than outdoor air pollution or tobacco smoke (2.3 increased odds of developing COPD compared to those not exposed to biomass fuel).

C.2 Common symptoms of COPD include shortness of breath, fatigue, an ongoing cough or a cough that produces a lot of mucus, wheezing and chest tightness. COPD in most cases, results in the following changes in the lungs that reduce the flow of air in and out of lungs and deprive the body of much-needed oxygen:

- air sacs and airways lose their ability to stretch
- the walls of the air sacs are destroyed
- the walls of the airways become thickened and inflamed
- airways become clogged with mucus.

C.3 COPD has a considerable impact on patients. Symptoms such as breathlessness, cough, wheezing, chest tightness, sputum production and fatigue are associated with activity limitation which may lead to a loss of independence and to anxiety and depression. These worsen over a period of time leading to activity limitation and eventually to restricted mobility and a loss of independence. In severe COPD, taking a few steps could make the patient breathless. Finally patients develop respiratory failure and die due to this or associated heart disease. COPD is

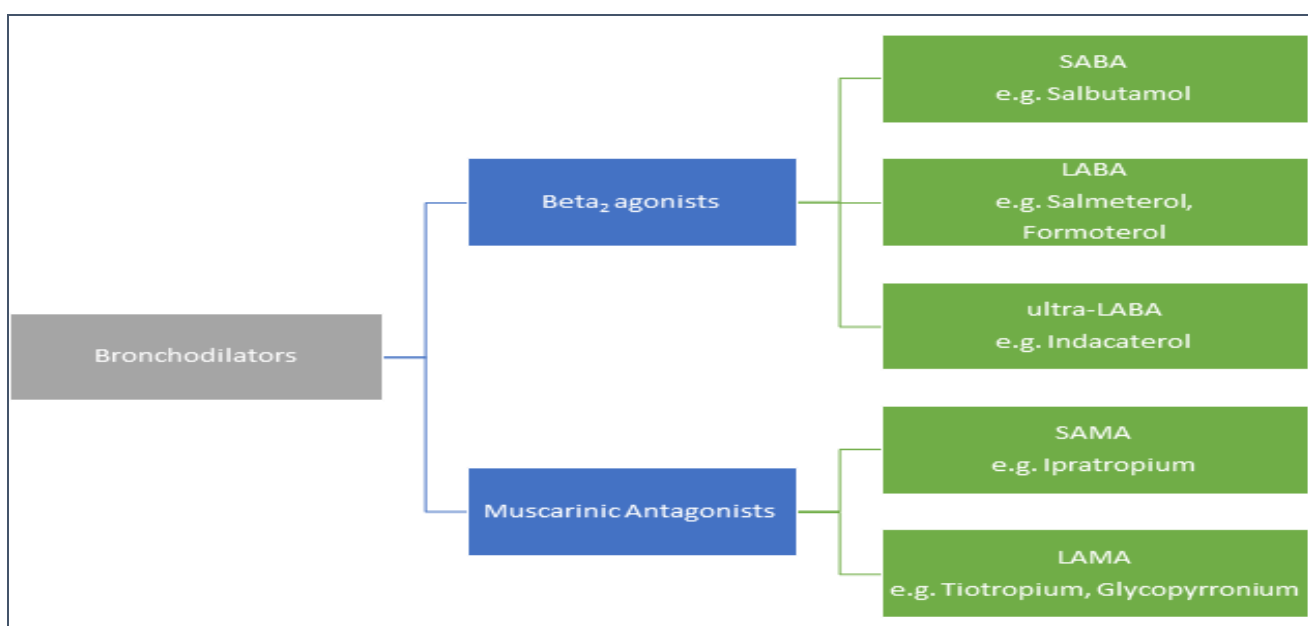
also associated with a major economic burden, in terms of the direct costs to healthcare systems and indirect costs due to disability, economic inactivity and costs to family and caregivers.

- C.4 As per the WHO, "Chronic obstructive pulmonary disease (COPD) is a lung ailment that is characterized by a persistent blockage of airflow from the lungs. It is an under-diagnosed, life-threatening lung disease that interferes with normal breathing and is not fully reversible." Statistics show that in a developing country like India, most often, respiratory ailments are unreported and undiagnosed. Further, it is primarily due to the fact that the symptoms of COPD are quite like the symptoms of Asthma and other respiratory diseases, that COPD often gets misdiagnosed as Asthma, and therefore the method of treatment adopted is incorrect or ineffective. Other reasons for incorrect diagnosis are the misconceived notion that COPD is caused only due to tobacco and cigarette consumption, as also due to under-utilization of both Spirometry (which is diagnostic tool) as well as Indacaterol.
- C.5 The aim of treatment in COPD, is to prevent and control symptoms, to reduce the frequency and severity of exacerbations, to improve health status, and to improve exercise tolerance. Bronchodilators, which reduce airflow limitation, are central to the relief of symptoms in COPD, and improve exercise tolerance. Regular use of a long-acting bronchodilator can reduce the rate of exacerbations, which, although not prospectively demonstrated, could potentially reduce the risk of mortality. Indeed, optimizing bronchodilation is essential to the overall management of COPD.

- C.6 Bronchodilators, i.e. medicines which make breathing easier by relaxing the muscle in the lungs and widening the airways in the lungs, are central to the management of COPD. There are two kinds of bronchodilators prescribed for COPD, namely Beta2-adrenergic receptor agonists and Muscarinic receptor antagonists/Anti-Cholinergics. These essentially differ in their mode of action. The Beta2-adrenergic receptor agonists act on a particular Beta2-adrenergic receptor in smooth muscles, increase the activity of the said receptor which ultimately causes smooth muscles in the airways to relax. On the other hand, the Muscarinic receptor antagonists/ Anti-Cholinergics cause the desired ameliorative effect by decreasing the activity of the said receptor which in turn results in the same end result as achieved by the action of the Beta2- adrenergic receptor agonists. Hence, though the modes of action are different, the end result achieved is similar, namely, widening the airways in the lungs.
- C.7 These bronchodilators can be further classified into Long-Acting Bronchodilators and Short-Acting Bronchodilators. The difference between these two kinds of classes is in the duration of action and hence, the frequency of dosage to be required for treatment. For a particular dosage, the Long-Acting Bronchodilators have a more prolonged effect on the lungs and hence, are required to be taken at a lower frequency in comparison to the Short-Acting Bronchodilators.
- C.8 At all severity stages, short acting inhaled bronchodilators are recommended on an as-needed basis for relief of intercurrent breathlessness (dyspnea). For disease of moderate severity accompanied by persistent symptoms or limitation of physical activity due to dyspnea, maintenance daily therapy with at least

one long-acting inhaled bronchodilator (either the once-daily long-acting antimuscarinic (LAMA) tiotropium, and/or a twice-daily long-acting beta-agonist (LABA)) is recommended. Combination therapy with long-acting inhaled bronchodilators of different classes (LAMA and LABA) which act by different mechanisms is recommended for patients with moderate disease who do not respond satisfactorily to a single long-acting agent. For severe and very severe disease associated with frequent exacerbations of COPD, the addition of inhaled corticosteroids (ICSs) is recommended. Such added therapy is usually in the form of a fixed combination of a LABA and an ICS.

C.9 The bronchodilator options for COPD are tabulated below for ease of reference:



LEGEND:

LABA: Long Acting Beta 2 Adrenergic Agonist
 SABA: Short Acting Beta 2 Adrenergic Agonist
 SAMA: Short Acting Muscarinic Antagonist
 LAMA: Long Acting Muscarinic Antagonist

C.10 In view of the increasing prevalence of COPD and the negative impact of the disease on patients, healthcare systems and society at large, there is a pressing need for new, more effective, and more convenient therapies. In addition to new treatments, which should offer better efficacy with respect to improvements in lung function and symptom relief, it has been noted that an important step in simplifying COPD management and improving compliance with prescribed therapy would be to reduce the dose frequency, making treatment more convenient for patients.

D. DISADVANTAGES OF THE EXISTING TREATMENT

D.1 The disadvantages faced by patients and practitioners while adopting the abovementioned therapies as briefly discussed below:

- a) Salmeterol and Formoterol and their available combinations though efficacious are found not to be convenient for patients as they have to be administered twice a day, on a daily basis for long term; and therefore, the twice daily dosing may hamper compliance which in turn may cause suboptimal symptom control;
- b) Similarly, Tiotropium, which as discussed hereinabove is a muscarinic antagonist, is relatively slow in onset of action.

D.2 In view of the increasing prevalence of COPD and the negative impact of the disease on patients, healthcare systems and society at large, there is a pressing need for new, more effective, and more convenient therapies for combatting COPD. In addition to new treatments, which should offer better efficacy

with respect to improvements in lung function and symptom relief, it has been noted that an important step in simplifying COPD management and improving compliance with prescribed therapy would be to reduce the dose frequency, making treatment more convenient for patients.

- D.3 Indacaterol provides once-daily dosing, fast onset of action and sustained efficacy assuring optimal bronchodilation throughout 24 hours. It has demonstrated efficacy similar to or better than that of current standard bronchodilators. Thus, it offers a new option over other LABAs and anticholinergics that are currently indicated for the treatment of COPD.
- D.4 Combination treatment with LABA and LAMA is recommended as option by the 2013 version of the GOLD COPD guidelines when symptoms are not improved with single agent in patients classified as group B (low risk, more symptoms). Similarly, the combination of a LABA and a LAMA in addition to an inhaled corticosteroid is recommended as alternative to a single-agent LABA or LAMA plus an inhaled corticosteroid in patients classified as group C (high risk, less symptoms). The GOLD 2013 states that "Both long-acting anticholinergic and long-acting beta 2 agonists reduce the risk of exacerbations, and although good long-term studies are lacking, the principle of combination treatment seems sound". Indacaterol can thus be the preferred once-daily add on to Tiotropium to those patients who may benefit with combination bronchodilator therapy.

E. SUMMARY OF THE PATENTS OWNED BY NOVARTIS PERTAINING TO INDACATEROL: A CLASSIC CASE OF EVERGREENING

- E.1 As mentioned above, Indacaterol is the INN name of the drug in question, which is represented by the chemical name (R)-5-[2-[(5,6-Diethyl-2,3-dihydro-1H-inden-2-yl)amino]-1-hydroxyethyl]-8-hydroxyquinolin-2(1H)-one. The said drug has been granted patent protection in India by way of Patent no. 222346 (hereinafter referred to as IN '346), titled "Beta 2 Adrenoceptor Agonists" and is owned by Novartis AG. Novartis holds a large number of patents in India. Its core therapeutic specialities include *inter alia* oncology, hypertension, metabolism, respiratory, neuroscience and ophthalmics.
- E.2 Cipla reserves its rights to avail its remedies under law to challenge the validity of the said patents as it believes the same to be non-inventive and obvious. The present representation is without prejudice to any other proceedings that may be initiated by Cipla against the Patents granted to Novartis.
- E.3 Indacaterol was approved by the European Medicines Agency (EMA) and is available for sale under the trade name ONBREZ. The United States Foods and Drugs Administration (US FDA) also approved the said drug, which is sold under the trade name ARCAPTA. Indacaterol is a preferred drug prescribed specifically for the treatment of COPD, and is considered to be more effective than the other Beta Andrenoceptor Agonists such as FORMOTEROL and SALMATEROL etc. The said drug is to be administered once a day.

E.4 Indacaterol is the subject matter of five (5) patents granted in favour of Novartis. The details of the said patents pertaining to Indacaterol are elucidated hereinbelow:

A. IN222346 titled "Beta 2 Adrenoceptor Agonists"

a) The first patent for Indacaterol is **IN222346** (hereinafter, IN'346) granted to Novartis. The said patent relates to "Beta 2 Adrenoceptor Agonists". This is the first patent relating to Indacaterol.

b) Relevant details of the patent are given below

Patent No.	IN222346
Filing Date	28.11.2001
Application No.	IN/PCT/2001/1673/CHE
Title	Beta 2 Adrenoceptor Agonists
Publication Date	21.11.2008
Grant Date	05.08.2008
Intl PCT Application	PCT/EP2000/005058
Intl Filing Date	02.06.2000
Priority Date	04.06.1999
Grantee	Novartis AG

B. IN 214320 titled 'a pharmaceutical composition for the treatment of inflammatory and obstructive airways diseases'

a) Patent number **IN 214320** is the second patent also granted in favour of Novartis. This patent relates to 'a pharmaceutical composition for the treatment of inflammatory and obstructive airways diseases'. The details of this patent are as follows:

Patent No.	IN214320
Filing Date	02.06.2003
Application No.	856/CHENP/2003
Title	A Pharmaceutical Composition Composition For The Treatment Of Inflammatory And Obstructive Airways Diseases
Publication Date	31.03.2008
Grant Date	11.02.2008
Intl PCT Application	PCT/EP2001/014122
Intl Filing Date	03.12.2001
Priority Date	04.12.2000
Grantee	Novartis AG

- C. Novartis also owns three more patents, viz. **IN210047**, **IN230049** and **IN230312**, for the process of producing the relevant compound and its related, as well as, intermediate salts. The details of these patents are below:

Patent No.	IN210047
Filing Date	01.09.2004
Application No.	1944/CHENP/2004
Title	Process for Preparing 2- Aminoindan Derivatives
Publication Date	14.12.2007
Grant Date	17.09.2007
Intl PCT Application	PCT/EP2003/002366
Intl Filing Date	07.03.2003
Priority Date	08.03.2002
Grantee	Novartis AG

Patent No.	IN230049
Filing Date	30.09.2005
Application No.	2474/CHENP/2005
Title	A Process for the Preparation of 5-(Haloacetyl)-8-(Substituted Oxy)-(1H)-Quinolin-2-ones
Publication Date	27.03.2009
Grant Date	24.02.2009
Intl PCT Application	PCT/EP2004/03479
Intl Filing Date	01.04.2004
Priority Date	02.04.2003
Grantee	Novartis AG

Patent No.	IN230312
Filing Date	26.08.2005
Application No.	2065/CHENP/2005
Title	A Process for Preparing 5-[(R)-2-(5,6-Diethyl-Indan-2-ylamino)-1-Hydroxy-Ethyl]-8-Hydroxy-(1H)-Quinolin-2-one Salts
Publication Date	27.03.2009
Grant Date	25.02.2009
Intl PCT Application	PCT/EP2004/01981
Intl Filing Date	27.02.2004
Priority Date	28.02.2003
Grantee	Novartis AG

E.5 Owing to these patents Novartis claims the exclusive rights to the pharmaceutically significant drug, Indacaterol, also also to

the processes of manufacturing the drug and all its relevant intermediates. Cipla believes that such exclusivity is contrary to law due to various reasons including lack of inventive step, being obvious inventions and also most importantly lack of “working” of the drug in the country.

- E.6 Further, it is relevant to note that a perusal of the abovementioned patents reveal that there is a complete attempt being made by Novartis to indulge in Evergreening. This is evident from the fact that after having filed the first patent that allegedly claims Indacaterol, several subsequent related patent applications have also been filed by Novartis, at a later stage, in a completely unjustified and illegal attempt to increase the term of protection over the said patents, therefore, resulting in extending the monopoly enjoyed by Novartis much beyond the term of the first patent.
- E.7 Moreover, it is relevant to note that Indian law expressly bars evergreening, and a large number of amendments were made to the Act in the year 2005, with the dual purpose of curbing the menace of evergreening, as also to ensure access to medicine. These are the fundamental tenets of the patent regime in India, and Novartis has in fact, flouted both these well established principles of law.

F. QUANTITY OF INDACATEROL IMPORTED BY THE PATENTEE

- F.1 Indacaterol is not manufactured anywhere in India by Novartis or any of its licensees. The said drug is only imported into India through Novartis’ licensee, being a pharmaceutical company

known as Lupin Limited. As per the Form 27 filed by Novartis before the Indian Patent Office for IN '346, the following are the quantities of Indacaterol imported through Lupin Limited for 2012 and 2013:

Year	Quantity Imported (In Units)	Sales Figures (In Rupees)
2012	53144	3.36 Crores
2013	32551 (300 mcg)	1.96 Crores
	21314 (150 mcg)	1.28 Crores

Copies of the Form 27s as filed by Novartis for the years 2012 and 2013 for In'346 as also for other patents being IN'047, IN'049 and IN'312, as available on the Patent Office website are annexed herewith as **ANNEXURE B (Colly)**. Interestingly, the figures for the year 2013 of subsequent patents are identical to those given for IN'346 and clearly shows that the subsequent patents are nothing but a bogey and a blatant attempt of evergreening. None of the patents are being actually worked in India and the Form 27s filed are completely misleading with false and incorrect data without any basis.

F.2 However, the IMS sales figures for Lupin Limited are given below:

Year (Period ending August)	Quantity Marketed (In Units)	Sales (In Rupees)	Combined Sales
2012	3872 (300 mcg)	Rs.63.66 lakh	Rs.91.67 lakh
	1704 (150 mcg)	Rs.28.01 lakh	
2013	3045 (300 mcg)	Rs.47.12 lakh	Rs.87.51 lakh
	2610 (150 mcg)	Rs.40.39 lakh	
2014	8648 (300 mcg)	Rs.133.82 lakh	Rs.2.14 Crores
	5165 (150 mcg)	Rs.79.92 lakh	

Copies of the relevant data from the IMS database are annexed herewith as **ANNEXURE C**.

- F.3 The abovementioned data reveals the following:
- a) That the IMS database does not reveal any sales whatsoever carried out by Novartis itself;
 - b) The figures reflected in the IMS data, which pertains to actual sales, are infact, lower than the figures reported to the Patent Office as evidence of importation of the drug. Therefore, the same suggests that not all the units that are shown to be imported as actually marketed by Lupin Limited.
- F.4 For one month, one patient will need 1 bottle of 30 capsules per month of Indacaterol which is hereby mentioned as "1 Unit". The number of patients tentatively suffering in India is about 1.5 crores. Current population of India is 121 crores. Therefore, approximately 1.23% of Indian population is suffering from COPD. The amount of Indacaterol required is 1.5 crores units per month. Assuming the patient takes it for 12 months, India

will need 1.5 crore x 12 Units per year. The said figure is 18 crores Units per year. However, the supply through imports by Novartis is approximately 54 Thousand units per year on an average (as per the Form27s filed with the Patent Office, which is publically available).

F.5 Therefore, it is evident from the above data, that a mere 0.03% of the requirement of the drug in India is being fulfilled by Novartis and Lupin Limited. Therefore, the percentage of the inadequacy in the requirement per year is a staggering figure of approximately 99.97%.

F.6 Further, it is pertinent to note that Cipla has been undertaking research and development pertaining to Indacaterol (which it is permitted to undertake by way of the provision of Section 107A of the Act). Further, the said product is being launched shortly by Cipla in New Delhi probably by the end of this week and shall be available for sale in New Delhi under the brand name UNIBREZ, with a view to satisfy the unfulfilled requirement of Indacaterol in India. A copy of the product packaging of the product under the mark UNIBREZ is annexed herewith as **ANNEXURE D.**

G. NO MANUFACTURE OF INDACATEROL IN INDIA BY THE PATENTEE

G.1 It is significant to note that though Novartis applied for the first Patent in India in the year 2001. The same was first approved by the European Medicines Agency (EMA) in 2009. However till date i.e., October 2014, no manufacturing of the said drug has been taken up neither by Novartis nor by its licensee Lupin

Limited within the territory of India. As per the IMS records as well as the records submitted by Novartis before the Patent Office (in the form of Form 27), it is evident that Indacaterol under the brand name ONBREZ is imported by Novartis through its licensee Lupin Pharma only, and neither is the product manufactured independently by Novartis, nor through Lupin Limited or any other licensee.

G.2 Further, it is relevant to note that the law in India requires that all patents be 'worked' within the territory of India, and while in some cases, adequate quantity of imports may qualify as working, depending on the facts and circumstances of each case, the present case is one in which the patents in question have not been worked at all, and the requirement of the public has not been fulfilled at all.

G.3 Further, as mentioned above, Cipla has been undertaking research and development pertaining to Indacaterol (which it is permitted to undertake by way of the provision of Section 107A of the Act), and at present, is in a position to launch the drug that would satisfy the unfulfilled requirement of Indacaterol in India. The said drug will be launched shortly under the brand name UNIBREZ ROTACAPS by Cipla in Delhi by the end of this week. Further, the said drug as launched by Cipla is manufactured in India, in the manufacturing units owned and overseen by Cipla.

H. PRICING OF THE PRODUCT IN INDIA

H.1 The estimated cost of the drug Indacaterol as imported and sold by Lupin Limited, under the trademark Onbrez (as a licensee of

Novartis) is about Rs.2000/- per month per patient. On the contrary, the proposed drug of Cipla under name UNIBREZ would be costing approximately Rs. 400 per month. Therefore, based on the abovementioned data, the comparative pricing data is given below:-

Brand	Company	Strength	MRP per 10 caps
Onbrez	Lupin Limited	150 mcg	Rs.677.00 [420% more expensive than the price at which the drug is being sold by Cipla]
Unibrez	Cipla Limited	150 mcg	Rs.130.00

H.2 Therefore, from the abovementioned data, it is evident that the drug as launched by Cipla would not only fulfil the requirements of the public, meet the interest of public health and access to medicine, but would also do so in an economical manner so as to ensure the affordability of the drug.

I. CONTINUATION OF THE PATENTS ON THE REGISTER OF PATENTS PREJUDICIAL TO PUBLIC INTEREST

a. Analysis of number of patients versus quantity of drug imported:

a.1 It is important to note that the total burden of COPD in India is about 14.84 million in 2011 (approximately 15 million, taken for convenience in present representation). Estimates suggest that India contributes a significant and

growing percentage of COPD mortality which is estimated to be amongst the highest in the world as published in the article titled "*Chronic Obstructive Pulmonary Disease: Indian Guidelines and the Road Ahead, 2013*". A copy of the said article, authored by Mr. Parvaiz Koul, Director of Internal and Pulmonary Medicine, Institute of Medical Sciences, Srinagar, is annexed herewith as **ANNEXURE E**.

a.2 Moreover, the fact that the number of patients suffering from COPD is increasing every year at a rapid pace is a further cause of concern, and urgent and effective remedial action is required. While an article published in the year 2001 estimated the number of patients suffering from COPD in the year 1996 at about 1.2 crore, the said figure had increased to about 1.5 crore in 2012. The article titled "*A Review of Population Studies from India to Estimate National Burden of Chronic Obstructive Pulmonary Disease and its Association with Smoking (2001)*" authored by Dr. S K Jindal is annexed herewith as **ANNEXURE F**. Dr. S K Jindal, is the Head of Department, Pulmonary Medicine, of the Postgraduate Institute of Medical Education & Research (PGIMER) Chandigarh, and has many publications in the field of respiratory diseases to his credit.

a.3 Given that a large number of publications, as mentioned below, suggest that the number of patients suffering from COPD in India are about 1.5 crore, it becomes evident that the quantities of units as imported by Novartis and Lupin are woefully inadequate and do not even begin to fulfil the need of the drug in India.

b. COPD has reached the magnitude of an epidemic in India:

- b.1 An epidemic is defined as a disease which occurs in community at a particular time and spreads widely in that short period of time to a great extent. However, COPD continues to be a chronic non communicable disease which imparts a continuous burden on the healthcare infrastructure of the country. Though it is not related to sudden outburst or limited to a shorter time period, still it can be classified as epidemic because of the huge burden which it poses to the society. The huge and widespread burden of the disease is attributable to economic loss, disease morbidity and immature mortality.
- b.2 The Indian Council of Medical Research (ICMR) took the initiative to study the epidemiology of COPD and sponsored the Indian study on epidemiology of Asthma, respiratory system and chronic bronchitis (INSEARCH) and conducted the Phase-I and Phase-II study. The Phase-I study was from four centers being Chandigarh, Delhi, Kanpur and Bangalore which reported the overall prevalence rates of 5.0 and 3.2% respectively in men and women of and over 35 years of age. A copy of the Report of the ICMR INSEARCH study titled "*Indian Study on Epidemiology of Asthma, Respiratory Symptoms and Chronic Bronchitis in Adults (INSEARCH)(2012)*" is annexed herewith as **ANNEXURE G**. The said study, authored by Dr. S K Jindal was published in the International Journal of Tuberculosis and Lung Disease.

- b.3 In fact, in another publication, Dr. Jindal has suggested that the prevalence of COPD in India at present is so rampant that it has become an epidemic, which is largely unrecognized, and therefore, untreated. A copy of the said article, titled "*COPD: The unrecognized Epidemic in India*" by Dr. SK Jindal relying upon the ICMR and INSEARCH data is annexed herewith as **ANNEXURE H**. The said article was published in JAPI, which is one of the premier medical journals in India, and is published on behalf of the Association of Physicians of India (API).
- b.4 COPD is among the top ten causes of disease burden in India. In a study published in 2012, the 'Indian Study on Epidemiology of Asthma, Respiratory Symptoms and Chronic Bronchitis in Adults' (INSEARCH) has estimated that about 7% of deaths annually are a result of Chronic Respiratory Diseases (CRD) (marked as **Annexure G** above). One of the most prevalent CRDs in India is COPD, and a major segment of the abovementioned figure is attributed to COPD. Further, according to the said study, a total of 1,69,575 individuals were surveyed across the length and breadth of the country. From this sample set, it was found that 3016 persons, i.e. 3.5% of the population suffered from Chronic Bronchitis or COPD. Therefore, the national burden was thus estimated to be 14.84 million. This figure shows a marked increase from approximately 12 million people who were suffering from COPD in the year 1996.
- b.5 Shockingly, according to the WHO, COPD is the cause of death of more people than HIV-AIDS, Malaria and

Tuberculosis all put together in the South East Asian Region. This data holds true for India as well, with about 50 Lakh people losing their lives to COPD every year, which is more than the loss of lives due to HIV-AIDS, Malaria, dengue, iodine deficiency, cancer and Tuberculosis. What is even more worrisome is that according to WHO estimates, this figure is likely to continue to rise for the next two decades (while the figures for HIV-AIDS, Malaria and Tuberculosis are expected to fall). Further, it is most relevant to note that the estimated economic loss to India due to COPD in the year 2005 was Rs. 35,000 Crore. With increase in the number of patients suffering from COPD, this figure is, correspondingly, on the rise. Interestingly, this figure is higher than the total budget of the Ministry of Health and Family Welfare of India, which was Rs. 25,154 crore for the year 2010-11. The article/publication titled "*India needs a National COPD Prevention and Control Programme, 2012*" is annexed herewith as **ANNEXURE I**. The author of the said article, Dr Sundeep Salvi, MD, DNB, PhD (UK), FCCP (USA) is the Director, Chest Research Foundation, Pune, India, and is also a Visiting Faculty at Imperial College, London, UK and Johns Hopkins University, Baltimore, USA. The said article was published in JAPI, which is one of the premier medical journals in India, and is published on behalf of the Association of Physicians of India (API).

- b.6 Similarly, it is relevant to note that studies suggest that apart from the already increased number of patients suffering from COPD, the said figure is likely to rise to 2.2 crore in the next few years. The report titled "*COPD in*

India: Iceberg or Volcano? (2012)” authored by Prof. Arvind Bhome, published in the Journal of Thoracic Disease is annexed herewith as **ANNEXURE J**. Prof. Arvind Bhome is a Professor of Pulmonary Critical Care Sleep Medicine, B V Medical College, Pune. The Journal of Thoracic Disease was founded in December 2009, and indexed in PubMed in December 2011 and Science Citation Index SCI in February 2013. The Journal is also endorsed by the International COPD Coalition (ICC).

b.7 The data provided by ICMR, estimated that the number of patients in India is 12.36 million in year 2005. The same has now grown to 14.84 million (i.e approximately 1.5 crore) in 2011 (as also corroborated by the above INSEARCH paper, annexed as **ANNEXURE G** above). The same, if compared to the quantity of the drug being imported by Novartis through Lupin Limited (as revealed from the Form 27s filed by Novartis before the Patent Office), the deficiency as calculated above in Para G.4 is 99.97%.

b.8 Therefore, it is clear that it is becoming increasingly imperative to check the increasing growth of COPD not only with a view to ensure better diagnosis and treatment of the patients who suffer from COPD, but also to reduce the economic burden imposed on the state due to the rampant prevalence of COPD.

c. Necessity of the availability of the drug

c.1 As has been shown above, Indacaterol is the preferred drug over other beta adrenoceptor agonists due to the fact that it

has to be consumed only once a day, as also the fact that it has higher potency and prolonged effect as compared to other beta adrenoceptor agonists. As per the above data there is shocking lack of availability of Indacaterol in India for the patients, afflicted by a chronic disease that has attained the magnitude of an epidemic. Despite the accepted benefits of the drug, the practitioners themselves are not able to prescribe the said drug due to the abysmally low quantity of the drug available to the public and the said quantity makes it practically impossible for patients to obtain the said drug.

c.2 The lack of availability of the said drug is because of the following reasons:-

- i. A very limited amount of drug is imported by Novartis through Lupin Limited.
- ii. Neither Novartis nor Lupin Limited manufactures the drug in India.
- iii. Lupin Limited sells the drug mostly to Government Institutions and the drug is not available across all chemists.
- iv. Lupin is not even fully selling what it is being imported by Novartis.
- v. The price of the drug is very high and the MRP of Novartis for Onbrez is approximately Rs.2000/- per month per patient.

d. Patentee's conduct is "mischievous to the State" and is also "prejudicial to the interest of the public"

d.1 As mentioned above, Novartis is the registered owner of patent No.IN'346 and other related patents in India. The patentee is neither manufacturing the products by itself nor manufacturing through its licensee. Even the alleged imports are grossly inadequate and do not satisfy the requirements of the general public owing to the large amount of patient population that is suffering from COPD, and therefore ought to be given ready access to suitable and adequate medication for the same. The patent having been applied for in 2001, and having been granted in 2008, more than thirteen years have lapsed since the filing of the application and six years have lapsed since grant. Therefore, Novartis had adequate time to show its *bona fide* intention to work the patent in India. Further, Novartis does not have any manufacturing plants in India, and has made not sizable investments in India in terms of Research and Development.

d.2 The conduct of Novartis is mischievous inasmuch as by filing five patents relating to the same or similar substance, the purpose appears to be to simply extend the monopoly by showing small quantities of import and ensuring that the Indian public does not benefit from the reasonably affordable drugs manufactured in India. This appears to be a clear case of Evergreening, and a complete illegal method of gaining monopoly with no intention whatsoever of working the same, and providing access to medicine in India.

d.3 A perusal of the product of Novartis being sold in India, under the brand name ONBREZ reveals the following:

Manufactured by:	Novartis Pharma Stein AG
Imported and Stickered by:	Novartis Healthcare Private Limited
Marketed by:	Lupin Ltd

d.4 There is no reason whatsoever for Novartis to be importing drugs manufactured in Switzerland when the same can be manufactured in adequate quantities to serve the needs of the Indian public. Import of products manufactured in Switzerland obviously results in sky-rocketing prices of the drugs out of the reach of the common man. Importing by a subsidiary of Novartis in small quantities and sale of even smaller quantities constitutes mischief and hence the exclusive rights deserve to be revoked in the interest of the general public. In fact, it is relevant to note that Cipla is manufacturing its drug in India itself, resulting *inter alia* in the price difference reflected above, and thereby aiding in ensuring access to medicine and large scale availability of the drug in India.

d.5 The law-makers had exactly such situations in mind while enacting Section 66 and Section 92 of the Patents Act. While in some situations import could constitute working, however in the facts of the present case when respiratory drugs are made by most companies in India and there is adequate expertise, there is no reason for not manufacturing in India.

d.6 Consequently, IN '346 and other patents have not been worked in India by the patentee and hence the nature of exercise of rights is abusive and prejudicial to public. The said patents were granted in favour of Novartis in 2008 onwards and thereafter and till date no endeavour has been made by Novartis to establish itself in India with a view to ensure that the said patents are worked in India.

d.7 The entire purpose of granting a patent, as mentioned above, is to reward innovation. However, the same cannot be done at the cost of public health, public interest and right of public to life and a better quality of life which is granted in Article 21 of the Constitution of India. The purpose of granting patent protection, apart from rewarding innovation, is also to ensure and facilitate the Transfer of Technology. Since there has been no manufacture under IN'346 in India by Novartis, there is no technology transfer whatsoever and Novartis is only making undue gains and resorting into unreasonable practices restraining trade and also adversely affecting the international transfer of technology.

d.8 Further, Article 7 of the TRIPS Agreement clearly vouches for and provides for transfer and dissemination of technology as an objective. Article 30 of the TRIPS Agreement also provides rights to the countries to provide limited exceptions to the exclusive rights conferred by a patent. In the Doha declaration of WTO in November 2001, the TRIPS Agreement was clarified with respect to the issues of availability of medicines. It was further clarified

that TRIPS Agreement ought to be read in the light of the object and purpose of the Agreement. The objectives are related to social and economic welfare and balance of rights of obligations. However, it is to be seen that whether the said objectives have been achieved by Indian system or not. Article 7 of the TRIPS Agreement is reproduced hereinbelow for the sake of reference:

“Article 7: 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 producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

J. REQUIREMENT OF PUBLIC INTEREST NOT SATISFIED BY THE PATENTEE

- J.1 It is the obligation of every Patentee to exercise its rights in a manner which is in consonance with rewarding innovation and dissemination of the knowledge. However, the mode of exercise of the patent rights cannot be in a manner which is contrary to the avowed purpose behind grant of patents itself. While rewarding innovation, patentees are expected to use the innovation for the benefit of the public. By not manufacturing the drug or making it available on a commercial scale, Novartis has exercised its rights contrary to the statutory purpose. In respect of pharmaceutical inventions, the discharge of the above said obligation becomes all the more important as the same is essential for satisfying the public health requirements of the state. It is also pertinent to note that mere importation of the

drug without taking steps to ensure manufacturing of the said drug within the territory of India goes against the very grain of the rightful exercise of the right under the Patents Act.

J.2 The Report on the Revision of the Patents Law by Shri Justice N. Rajagopala Ayyangar made public in September 1959 (Hereinafter referred to as the "Ayyangar Committee Report" or the "said report") constitutes the backbone of Modern Patent Law in India and the present Patents Act is significantly based, both in letter and in spirit, on the principles laid down in the said report. The said report, in paragraphs 33 to 35, describes the detrimental effects of non-working of patents of foreigners in India. A copy of the Ayyangar Committee Report is annexed herewith as **ANNEXURE K**. The relevant paragraphs are extracted herein below:

"... 33. I shall next proceed to consider the cost to the country, particularly an under-developed country like India, of the grant of these patents which the patentee has no intention, of working in this country. These patents may be broadly classified under two heads: (1) where a particular invention is not patentable under the laws of the patentee's home country but it is patentable under the Indian Patents Act; (2) where an invention is covered by patents in several countries of which India is one but the manufacture is carried on either in the home country of the patentee or in some other country outside India where he has obtained patent protection...

34. A well-known example under the first head where an invention is not patentable in the patentee's home country but is patented in India relates to patents for medicines and

drugs taken out by Swiss nationals in India. Where the substance is new but the process by which it is produced is not new, no patent can be obtained in Switzerland, whereas a claim for a new product made by the process which is not novel but is merely described in the specification may be patented in India. The result of the grant of an Indian patent to any Swiss firm in such circumstances would be to eliminate the competition of other Swiss firms from the Indian market. These firms, however, have freedom to compete with each other in the Swiss market but the benefit of this competition would not be available to the Indian consumer. As in most of the European countries, the law does not permit the patenting of chemical products, but allows only the processes for manufacturing those products to be patented, the situation for this country is greatly aggravated.

35. In the second type of cases listed above, a patent is applied for and obtained for the same invention in several countries of the world. This is done in order to ensure an export market to the producer as stated by Mr. Langner in the passage I have already quoted. As the right granted by a patent for an article includes the exclusive right to import the patented article from abroad (subject to general import restrictions, if any), the country selected by the patentee becomes the sole source on which the importing country has to depend for meeting its requirements. This acts detrimentally in more ways than one. In the first place, the existence of the patent prevents the importation of the product manufactured by the same or similar process from a country which might offer the article at a lower price. In this connection it might be pointed out that where the same patentee manufactures the same article in different countries, the price

of the product might not be the same in each country, and besides there is nothing to prevent a patentee from selling the same article at different prices in different markets based on local conditions as to demand, the availability of alternative products etc.”

(Emphasis Added)

J.3 Hence, based on this analysis, the detrimental aspects of granting patents to foreign companies which only import the patented drugs and do not manufacture in India cannot be overlooked.

J.4 Further, the safeguards in respect of working which necessarily need to be followed by the Patentee are described in Paragraph 38 of the said report and the same is extracted herein below:

“..38. I have already set out the considerations which are said to constitute the quid pro quo for the grant of the patent monopoly, namely; (1) the working of the invention within the country so as to result in the establishment in the country of a new industry or an improvement of an existing industry which would profitably employ the labour and capital of the country and thus increase the national wealth, and (2) disclosure to the public of the invention and the manner of its working so that on the expiry of the life of the patent the public are enabled to work the invention themselves and in competition with each other. Where the patentee has no intention of working the invention in this country either because he considers that this is not profitable or because he prefers to expand the production in his home country so as to achieve there greater efficiency and more production or is otherwise not interested in working the invention in India, the grant of

the Indian patent might tend to improve the economy of the patentee's home country but offers little advantage to us. Unless therefore the law provides for measures to be taken to compel the patentees to work the invention within the country, and these measures are effective to achieve their purpose, the social cost involved in the grant of the patent is not offset by any benefit to the community..."

(Emphasis Added)

J.5 Hence, working by manufacturing within the territory of India is one of the necessary considerations which needs to be satisfied by every Patentee. In fact, the Ayyangar Committee Report goes so far as to state that there should be a provision for revocation of a patent in the event of non-working as stated in paragraph 612 and the relevant extract of the same is reproduced hereinbelow:

"...612. I consider that the Indian law should contain a provision for revocation for nonworking. My draft of the clause follows in general the lines of section 42 of the U.K. Patents Act, 1949 and Section 109 of the Australian Patents Act, 1952. In the questionnaire which was issued dealing with the provisions as to compulsory licensing, I sought an answer to a query as to whether a provision on the lines of Section 42 of the U.K. Act was desirable. A considerable number of those who answered the questionnaire desired the inclusion of such a provision. Apart from the opinions expressed by these individuals or bodies, I am satisfied that unless there is a residuary power vested in the Controller to revoke a patent in the event of the invention not being worked to an adequate extent in the country, the compulsory licensing provisions

themselves might fail to achieve their purpose. Further I consider that the existence of such a provision might itself serve as an inducement to the patentees so to instruct their licensees with the details of such technical information as they have and to render them such assistance as might be needed to enable them to work the invention commercially and adequately so that the patent might remain in force and the patentees derive benefit from the royalties which the licensees should be paying during the term of the patent..”

The above passage highlights the position taken by Justice Ayyangar in respect of the essential requirement of working under the Patent Law.

J.6 Further, the invoked Section 66 of the Act and its relevance was discussed in the said report in paragraph 654 and the same is reproduced hereinbelow:

“.654. Clause 46—Revocation of patent in public interest.—Section 25 of the Indian Patents and Designs Act, 1911 enables the Government to revoke any patent by notification if they are satisfied that the continuance in force of the patent is contrary to the public interest. This provision is omitted in the Bill but I see no reason why it should be excluded. The power conferred may seldom be used but nevertheless it is a useful provision and taking into account the conditions now obtaining as well as future needs. I think it would be useful for the furtherance of the national economy. I have substantially reproduced its terms in Clause 46 in my draft. The following redraft gives effect to the above recommendation:—

"46. Revocation of Patent in public interest.—A patent shall be deemed to be revoked if the Central Government declares by notification in the Official Gazette that the patent or the mode in which it is exercised is mischievous to the State, or generally prejudicial to the public."

Hence, the importance of having the invoked provision in the statute book was clearly recognized in the said report.

J.7 It is important to note that the criteria like need for actual manufacturing in India, not mere importing and the broader public interest' requirement in India have been unequivocally submitted by India as its official stand with respect to its Patent Law in communications made to the General Agreement on Tariff and Trade (GATT). A copy of the relevant GATT communication is annexed herewith as **ANNEXURE L**. The relevant extract is reproduced herein below for the sake of convenience:

"... Working of Patents

9. The experience of developing countries would clearly point to four basic facts: firstly, patents are seldom worked in developing countries, even when it is techno-economically feasible to do so. Secondly, the working of the patent in the host country leads to saving of scarce foreign exchange (which is a major constraint to the economic development of developing countries) and the lowering of prices of products particularly in critical sectors such as food, pharmaceutical, agro-chemicals and the like. Thirdly, without the working of the patent, there can hardly be any transfer or diffusion of technology and the promotion of industrial activity in the host country. Fourthly, without working, patent protection would degenerate into a

mere monopoly for the importation of the patented article into the country, and a device for the reservation of the host country market by the patent owner.

10. Therefore, the working of a patent by the patent owner in the host country must be regarded as a fundamental obligation of the patent owner. The patent law should have a clear stipulation that patents are granted in order to secure that the inventions are worked in the host country on a commercial scale and to the fullest extent that is reasonably practicable without undue delay. The patent law should also make it unambiguous that the mere importation of a patented product does not amount to its working in the host country. The working of a patented invention should mean:
- where the patent has been granted in respect of a product, the making of the product
 - where the patent has been granted in respect of a process, the use of the process..."

"...Revocation of Patents

29. In order to mitigate the possible abuse of the patent system, the patent law should contain provisions for revocation of the patents in public interest. Specifically, where the host country Government finds that a patent has not been worked on a commercial scale or has been only inadequately worked in the country without any valid reason or that the patent is being used in a manner prejudicial to the public interest, the patent should be liable to revocation. Such revocation will, however, be done after giving an opportunity of hearing to the patent owner and will also be subject to judicial review..."

(Emphasis Added)

K. PROVISIONS INVOKED AND JUSTIFICATION THEREOF

K.1 Cipla is seeking to invoke Section 66 read with Sections 92(3)(ii) of the Act. Section 66 of the Act provides for revocation of a patent by the Central Government where the Central Government is of the opinion that the patent or the mode in which exercised by the patentee is mischievous to the State or is prejudicial to the public interest. After being satisfied that the patent is prejudicial to the public interest, the Central Government can make a declaration in the official Gazette to the effect of revoking the patent after giving an opportunity to the patentee to be heard.

K.2 Section 66 has been thoughtfully incorporated in the Patents Act so as to avoid the misuse of the exclusive right by the patentee at the cost of being unreasonable, mischievous and highly prejudicial to the public at large. Section 66 clearly emphasize that public interest has to be given importance over the monopoly given to the patentee.

L. SCHEME OF THE ACT PROVIDES FOR BALANCING THE PUBLIC INTEREST WITH THE MONOPOLY:

L.1 A patent is subject to invalidity at various stages as per the Act. The challenges to a patent can be in the form of counter claim in a suit or in the form of a revocation petition. The Act provides for mechanisms to control monopoly by a patent holder under Sections 66, 84 and 92 of the Act. It is clear from the scheme of the Act that public interest is not alien to the Act inasmuch as patents are granted for the benefit of the patentee as also the public at large. However, if the patented invention is not available to the public readily, in appropriate quantities or at reasonable affordable price, then the same defeats the very

purpose of the said specific provisions of the Act. The reasonable availability of a drug is undoubtedly a factor which is completely in public interest. The greater public access to highly recommended and efficacious drug ought to supersede and outweigh in the public interest above the monopoly granted to the patentee.

- L.2 In the instant case though the patent was granted in the year 2008, the patentee has, till date, not made any efforts in public interest to make the drug available to the patients by way of:-
- a. Manufacturing in India;
 - b. Manufacturing and importing the drug in reasonable quantities.
 - c. Assisting in transfer of technology to the territory of India.
- L.3 Article 21 of the Constitution of India gives the right to the citizens of India of life and which includes a better quality of life and good health. Access to treatment and in fact to appropriate treatment should not be only theoretical and illusory which make that drug which is invented for the very purpose of public health should be available to the public and not mere a tool for only benefiting the multinational companies and making undue gains.
- L.4 Section 66 gives important powers to the Central Government which ought to be exercised in the instant case inasmuch as COPD as demonstrated above affects about 1.5 - 2 crore people in India. There is a deficiency of 99.97 % of drug availability for the patients in India and the Central Government of India ought to take note of the same and act in accordance with the law.

L.5 Additionally, it has been demonstrated above COPD as a disease which has taken up the status of an epidemic and thus, under Section 92(3)(ii) satisfies the condition of circumstances of extreme emergency for the patients in India and the Central Government ought to take note of the same.

M. CIPLA'S READINESS TO LAUNCH

M.1 Cipla had already applied to obtain its drug approval in February 2014 for the drug Indacaterol. Cipla has huge expertise and specialization in the respiratory drug and has all the means and infrastructure for making the said drug which could be used by Indian patients. The insufficiency in the supply of the said drug can be made up by supply from Cipla and Cipla is keen on offering the said drug to the public for the benefit of public health.

M.2 The price at which the product is being sold by Cipla is fairly low and is to the amount of Rs.130/- in the comparison of Rs.677/- MRP per 10 capsules of Novartis. Cipla's drug is 80% cheaper amounting to better availability for the Indian Patients. Further, it is relevant to note that Novartis' drug ONBREZ is 420% more expensive than Cipla's drug under the mark UNIBREZ.

N. CONCLUSION AND PRAYER

In view of the arguments and contentions placed on record by way of the present representation, it is humbly prayed, that in exercise of powers under Section 66 as also Section 92 (3) the Central Government may revoke Indian Patents IN222346, IN230049, IN210047, IN230312 and IN214320 after giving opportunity to Cipla and Novartis to be heard.

This present representation is being signed by Mr. M C Misra, Resident Director, Cipla Limited, and filed by Singh & Singh Law Firm LLP, on behalf of Cipla Limited as instructed from Mr. R Gopalakrishnan, Head – Corporate Affairs and India Generics, Cipla Limited. Power of Attorney in favour of Mr. R Gopalakrishnan, as well as authorization letters in favour of Mr. S C Misra and Singh & Singh Law Firm LLP is filed herewith as **ANNEXURES M, N and O** respectively.

Settled by:
Mrs. Prathiba M Singh
Senior Advocate

Cipla Limited
Mr. S C Misra
Authorised Signatory

Drawn & Filed by:

Bitika Sharma & Anusuya Nigam
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