*** IN THE HIGH COURT OF DELHI AT NEW DELHI**

% *Order delivered on: 9th January, 2015*

+ **I.A. No.24863/2014 IN CS(OS) 3812/2014**

NOVARTIS AG & ANR ..... Plaintiffs

Through Mr.Gopal Subramanium, Sr. Adv. with Mr.Hemant Singh, Ms.Mamta R.Jha, Ms.Shilpa Arora & Mr.Talha Rahman, Advs.

versus

CIPLA LTD ..... Defendant

Through Mr.P.Chidambaram, Sr. Adv., Mr.Sandeep Sethi, Sr.Adv. and Mrs.Prathiba M. Singh, Sr.Adv. with Ms.Bitika Sharma, Ms.Anusuya Nigam & Mr.Vihan Dang, Advs.

CORAM:
HON'BLE MR.JUSTICE MANMOHAN SINGH

MANMOHAN SINGH, J.

1. The plaintiffs have filed a suit for permanent injunction restraining infringement of patent no.222346 granted under The Patents Act, 1970 (hereinafter referred to as "the Act") in favour of plaintiff No.1, rendition of accounts/damages, delivery-up etc. By this order I propose to decide the application under Order XXXIX Rule 1 and 2 read with Section 151 CPC.

2. Two plaintiffs have filed the present suit against Cipla Ltd. The plaintiff No.1 (the expression includes predecessor in business and title), Novartis AG is a company incorporated under the laws of Switzerland. The plaintiff No.2 (the expression includes predecessor in business and title) Novartis Healthcare Pvt. Limited is a company incorporated under The Companies Act, 1956 having its registered office at Sandoz House, Shiv Sagar Estate, Dr. Annie Besant Road, Worli, Mumbai-400018.

3. **CASE OF THE PLAINTIFF AS PER PLAINT**

i) The plaintiff No.1 is one of the famous companies in the world carrying on business through its affiliates and subsidiaries, inter alia, of manufacturing, marketing, research and development of high quality pharmaceutical preparations. Plaintiff No. 2 is one of the Novartis group companies ultimately held by plaintiff No.1.

ii) Lupin Ltd. is marketing products containing INDACATEROL, specifically INDACATEROL Maleate, which is the subject matter of the present suit patent under distribution and co-promotion agreement dated 22nd March 2012 with plaintiff No.2.

iii) It is alleged *inter alia* in para 4 of the plaint that the plaintiff No.1, or its predecessor companies, has been in the business of research, development, manufacture and sale of various pharmaceutical products for a period of more than 250 years. The plaintiff No.1 develops, manufactures and distributes hundreds of healthcare products in more than 150 countries.

The plaintiff No.1, along with the development of various pharmaceutical products, has also conducted countless clinical trials on its products. The plaintiff No.1 is strongly committed to research and development in order to invent new pharmaceutical products and plaintiff No. 1 spent USD 7.2 billion on pharmaceutical research and development in 2013 as has been published in the Annual Report of plaintiff No. 1 for the year 2013.

iv) It is averred in the plaint that the plaintiff No.1 is particularly engaged in ongoing research, invention, development and creation of various products and has acquired a worldwide reputation for safe and high quality pharmaceutical products, including drugs for the treatment of respiratory diseases such as chronic obstructive pulmonary disease (COPD). The products emanating from the plaintiffs are internationally known for their superior, high quality and technical excellence.

v) It is mentioned in the plaint that the plaintiff No.1 initiated its research program in the late 1990s for providing a maintenance therapy to maintain maximal bronchodilation throughout the day in patients with COPD. This would prevent the product needing to be repeatedly dosed. Hence, the product needed to provide long duration of action, preferably on single dose basis (as opposed to a rescue therapy which would have a fast onset but shorter duration of action). The plaintiff No.1 claims that the plaintiff invented a New Chemical Entity (NCE)

which is the subject matter of the present suit patent and is known with the International Non-Proprietary Name (INN) of INDACATEROL. This INN was published in the list of recommended INNs in 2005 by WHO (World Health Organisation). International Non-proprietary Names (INN) are names designated by the WHO which are given to new Active Pharmaceutical Ingredients (APIs) to provide a unique name per pharmaceutical drug to help avoid the confusion that can be caused by the number of different ways in which an API can be chemically named based on their chemical structure. Said novel and inventive compound, INDACATEROL, is a once-daily, ultra long-acting β_2- agonist approved for the treatment of chronic obstructive pulmonary disease (COPD). INDACATEROL is ultra long lasting as it provides up to 24-hour bronchodilatory effect (unlike long lasting β_2 agonists which only provide 12 hours bronchodilatory effect). It therefore allows for "once-daily administration" as compared to other bronchodilators available in the market which either require repeated dosage to maintain bronchodilation or are administered as a rescue therapy in cases of asthmatic attack or COPD condition.

vi) The suit patent as Indian Patent Application No. IN/PCT/2001/1673/CHE as of 28th November, 2001 as national phase entry of Patent Cooperation Treaty (PCT) International Application No. PCT/EP 2000/005058 dated 2nd June, 2000 claiming priority from UK Application No. 9913083.3 dated 4th

June, 1999. The INDACATEROL (International Non-Proprietary Name), the new chemical entity and compound, as well as its maleate salt, namely INDACATEROL Maleate in which INDACATEROL is the active moiety, are both protected as an invention under the suit patent No. IN 222346 in India.

vii) The bronchi and bronchioles are surrounded by thin layers of a type of muscle known as smooth muscle. The contraction and relaxation of this smooth muscle changes the diameter of the bronchi and bronchioles and alters the resistance to air flow through these airways into the lungs. Contraction of the smooth muscle surrounding the bronchi and bronchioles is regulated by a number of different biological mechanisms or 'pathways'. One of these pathways involves the release of a neurotransmitter called acetylcholine. Acetylcholine binds to receptors, known as muscarinic receptors, on the airway smooth muscle to bring about airway smooth muscle contraction (bronchoconstriction). If too much acetylcholine is released then excessive airway constriction can occur, as is seen in a number of respiratory diseases and particularly COPD. Another of the pathways acts as a brake on the acetylcholine pathway by promoting relaxation of the airway smooth muscle.

ABOUT CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD):

viii) The Chronic obstructive pulmonary disease (COPD) is a progressive disease of the lung characterized by chronically poor airflow. It typically worsens over time and symptoms

include shortness of breath, cough, and sputum production. Obstruction of airflow in the lungs results in debilitating bouts of breathlessness as well as extra pulmonary effects, such as weight loss and skeletal muscle wasting. Tobacco smoking is the most common cause of COPD, with a number of other factors such as air pollution and genetics playing a smaller role. In the developing world, one of the common sources of air pollution is from poorly vented cooking and heating fires. Long-term exposure to air pollution causes an inflammatory response in the lungs resulting in narrowing of the small airways and breakdown of lung tissue. The diagnosis includes determining the airflow as measured by lung function tests. There is currently no cure for COPD. Treatments have tended to treat symptoms and provide relief from exacerbations rather than by disease-modification. The main line of treatment for COPD is with inhaled bronchodilators which make breathing easier by relaxing the muscles in the airways to widen the airways. Bronchodilators are therefore so named as they dilate the bronchi (singular bronchus) and bronchioles, which are the tubes which conduct air to the lungs. Dilating these tubes decreases the resistance in the respiratory airway and increases airflow to the lungs. As a result bronchodilators reduce shortness of breath, wheeze and exercise limitation.

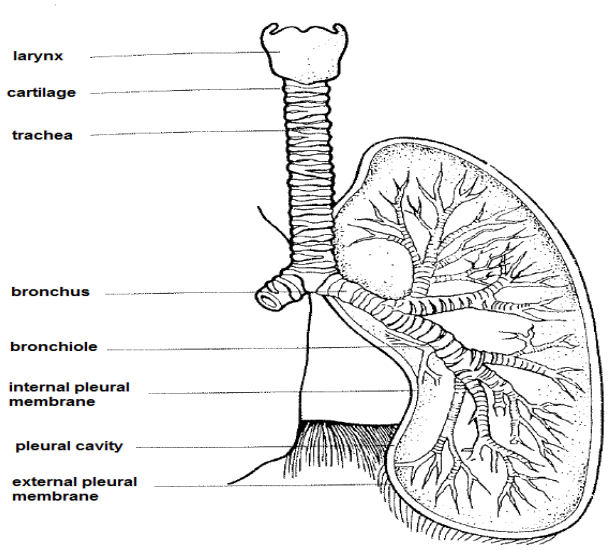


Diagram extracted from Biological Science 1 and 2(3rd edition) by Taylor, Green and Stout.

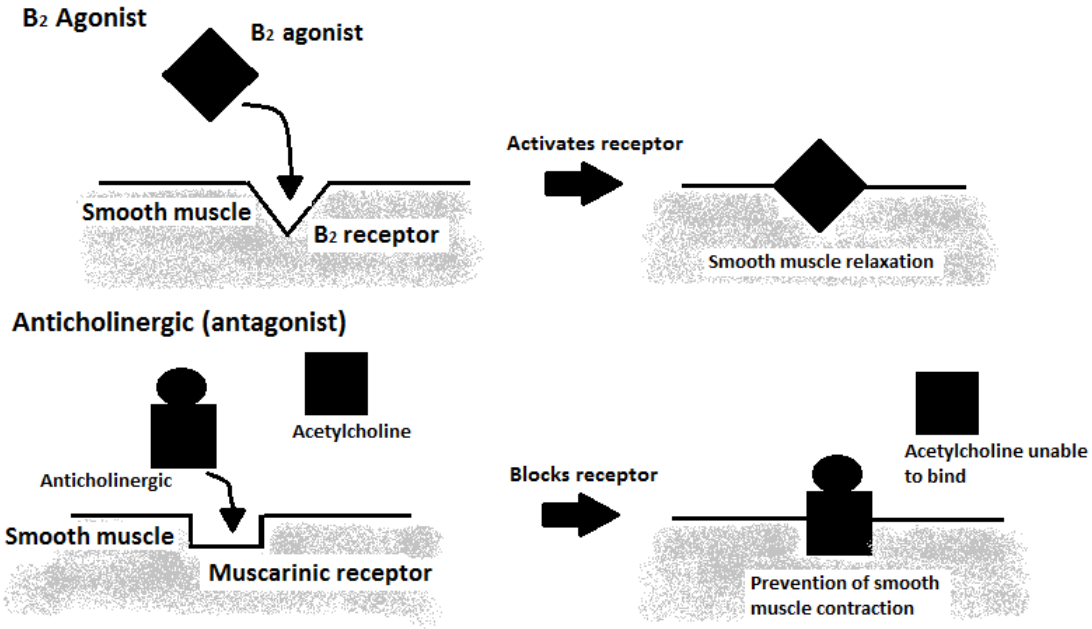
Types of Bronchodilators :

ix) In para 9 of the plaint, it is explained by the plaintiff that there are two major types of bronchodilators, β_2 agonists (also known as β_2-adrenergic agonists and β_2-adrenergic receptor agonists) and anticholinergics (also known as anti-muscarinics and muscarinic antagonists).

B_2 agonists are a class of drugs that bind to the B_2 receptors that line the airway and activate the receptor leading to smooth muscle relaxation, and dilation of the bronchial passages. As they activate the receptor to trigger the natural biological effect, they are known as agonists.

On the other hand, anticholinergics bind to the muscarinic receptor present in the airway and, do not trigger the natural biological effect, but instead they block the receptor to prevent

the naturally occurring molecule acetylcholine binding to the muscarinic receptor and triggering contraction of the airway. As a result less acetylcholine is able to bind to the muscarinic receptor and there is less contraction of the bronchial passages. As anticholinergics bind to a receptor and block the natural biological effect occurring they are known as antagonists.



x) Both B_2 agonists and anticholinergics exist in long-acting and short-acting forms. Short acting drugs work quickly (within 3-5 minutes) but they may only last 4-6 hours. These medicines are often given as reliever medicines because they bring quick relief from breathlessness. Long acting drugs give longer relief and may last up to 12 hours.

Short-acting bronchodilators are the first-line therapy for mild disease, with long-acting agents introduced as

maintenance therapy for patients with at least moderate disease.

Long-acting β_2-agonists and long-acting muscarinic antagonists as monotherapy or in combination as add-on therapy, are used to treat COPD in moderate or more severe cases. They may also be used in conjunction with other medications such as inhaled corticosteroids (ICS), antibiotics and others.

Examples of short-acting β_2 agonists that are used for the treatment of COPD include salbutamol and terbutaline which provide relief of symptoms for up to 6 hours. Long-acting β_2 agonists relieve symptoms for about 12 hours and these include salmeterol and formoterol.

Muscarinic antagonists used to treat COPD include ipratropium, a short-acting agent, and tiotropium that is long-acting.

xi) It is stated that there is a distinction between asthma and chronic obstructive pulmonary disease. The lungs in fact extend right from the bronchus and cover the bronchiole and also the area outlined by the internal and external pleural membranes.

xii) Chronic obstructive pulmonary disease (COPD) is a general term that describes progressive respiratory diseases including emphysema (gradual damage to air sacs) and chronic bronchitis, where it is characterized by decreased airflow over time and increased inflammation. Because asthma and COPD have a number of similarities, it can be difficult to distinguish

between them. However, after taking into account symptoms, medical history, a physical examination and results of medical tests, doctor can determine if either of these chronic diseases are at the root of your poor health. Both asthma and COPD may cause shortness of breath and cough. A daily morning cough that produces phlegm is particularly characteristic of chronic bronchitis, a type of COPD. Episodes of wheezing and chest tightness (especially at night) is more common with asthma.

xiii) Bronchodilators relieve symptoms by relaxing the muscle bands that tighten around the airways. This action rapidly opens the airways, letting more air come in and out of the lungs. As a result, breathing improves. Bronchodilators also help clear mucus from the lungs. As the airways open, the mucus moves more freely and can be coughed out more easily. Thus, the normal bronchodilator which is used when conditions like asthma (bronchial asthma) or respiratory inflammation, bronchodilators work in a short reach of the bronchus as they allow air to come in and out of lungs and hence mucus can move more freely and coughed out, this will ease up the situation. However, in respect of COPD patients even though they may be administered and have been administered for want of effective COPD therapy per se, as there is gradual damage to air sacs the effects have been simply to give symptomatic relief rather than the ability to open up the areas (as air sacs are destroyed) which are inside the air ways which would lead to oxygenation and increased ability of the lungs to be functional.

COPD patient is necessarily troubled with impaired lung functioning.

xiv) A bronchial asthmatic patient is also impaired but as in this condition the air sacs are not destroyed, mucus release out by cough eases the patient In respect of a COPD patient, it therefore becomes necessary that drug not only relieves symptoms but also prevents disease progression , improve exercise tolerance (for better quality of life) and improve health status, and reduce mortality. Therefore, INDACATEROL relieves symptoms by acting immediately with in 5 min of inhalation, and has sustained 24-hour duration of bronchodilator effect, this is due to its retention in the lipid membrane with ultra slow release, Thus it must be noticed that while there would be symptomatic relief when some bronchodilators are taken and lung function test would indicate marginal appreciation, however, in respect of COPD patients it is necessary to reach the lungs more effectively and that is possible only by the inventive compound namely INDACATEROL which ensures better and immediate relief, sustained 24 hours action, safer profile and excellent exercise endurance resulting in better quality of life in COPD patients.

xv) Thus the improved lung functioning “which is caused by INDACATEROL” is in fact a brilliant inventive step which provides a new once-daily option for patients with moderate and severe COPD with effective bronchodilation, fastest action, sustained 24 hrs bronchodilation, controls and prevents

symptoms, improves quality of life, improves exercise tolerance and comparable safety and tolerability compared to current therapies.

DEVELOPMENT OF INDACATEROL AS ALLEGED BY PLAINTIFFS

4. INDACATEROL can exist as different salt forms. Salts are ionic compounds that are formed when an acid reacts with a base. Salts are formed to improve physicochemical parameters, for instance enhance flowability or stability of the active ingredient for administration in the form of a drug. In the Plaintiff No. 1's product INDACATEROL is present as a salt form known as INDACATEROL Maleate. Different salts can be formed of the same compound and INDACATEROL can exist as other salt forms. However, in any of these salt form INDACATEROL is still the active moiety. Active moiety is defined as the part of the molecule that is responsible for the physiological or pharmacological action of the drug substance. In this case the maleate salt is used in the Plaintiff No.1's product as the salt is more stable and shows less degradation over time. In both INDACATEROL and INDACATEROL Maleate the active moiety is still INDACATEROL and it is this compound which has the effect to treat COPD in the body.

4.1 It is also the case of the plaintiffs that the pharmaceutical preparations comprising INDACATEROL Maleate are commercially manufactured and marketed as inhalation powders as a maintenance bronchodilator therapy for patients

who have chronic obstructive pulmonary disease (COPD). The said inhalation powder is marketed in capsules along with an inhaler which is packaged and retailed together. INDACATEROL Maleate inhaled powder product of the Plaintiff No.1 is recommended to be administered only by oral inhalation route and is only to be used with the co-packaged Breezhaler device. The onset of bronchodilation after inhalation of INDACATEROL Maleate inhalation powder is fast, with significant improvement seen within 5 minutes of inhalation. Further, the duration of action of the drug is up to 24 hours.

4.2 It is specifically mentioned in para 12 of the plaint the plaintiff took several years to research and develop INDACATEROL at huge financial investment running into hundreds of millions of US $ and requiring substantial human resources. Furthermore, for every pharmaceutical product that is successfully brought to market, a much higher number of promising candidates will ultimately fail at one stage or other of the development process. When the costs of these unsuccessful candidates are also taken into account, it has been estimated that the cost of a new chemical or biological entity is at least US $ 1 billion as is evident from reports published in various articles. According to a recent study by the Tufts Center for the Study of Drug Development, it costs drug makers $2.56 billion on average to bring a new medicine to market, more than double the price of 11 years ago. The cost comes from clinical trials that are larger and more complex, as

well as more drugs that fail in development, according to Tufts. Post-approval studies (for example to test new indications, formulations, dosage strengths and to monitor long-term side effects in patients) of $312 million boosts the full product lifecycle cost per approved drug to $2.87 billion, according to this study. A copy of this study has been placed on the record.

4.3 Pharmaceutical companies rely on the revenues generated from successful pharmaceutical products to invest in the research and development costs of new pharmaceutical products. The Plaintiff also invested huge amount in brand promotion, creating awareness for COPD management in consultation with doctors, hospitals, medical institutes, ESIC (Employees' State Insurance Corporation), CGHS (Central Government Health Schemes) etc.

4.4 With regard of approvals in US and use of drug in India, in para 14 of the plaint, it alleged that a drug for the treatment of COPD containing INDACATEROL as the active ingredient was approved by the European Medicines Agency (EMA) under the trade name ONBREZ on 30th November, 2009 and by the United States Food and Drug Administration (FDA) under the trade name Arcapta Neohaler, on 1st July, 2011. INDACATEROL (as its Maleate salt) was launched under the brand ONBREZ in India in the year 2010. The said product has been marketed in India since 2010 by way of import by plaintiff No.2 through its consignment sales agent, i.e. Novartis India Ltd., also an affiliate of plaintiff No.1. The said product is now

being distributed by Lupin Ltd. by way of purchase from plaintiff No.2 under distribution and co-promotion agreement dated 22nd March, 2012. INDACATEROL Maleate inhalation powder is manufactured and sold by wholly owned subsidiaries of the Plaintiff No.1, being Novartis Pharma Stein A.G., and Novartis Pharma A.G, respectively, both located in Switzerland. The plaintiff No.1 uses one manufacturing plant located in Switzerland in the district Stein, for manufacturing INDACATEROL Maleate inhalation powder to be distributed globally. This centralized manufacturing plant which is a state of art technology ensures that the plaintiff is saved the cost of manufacturing units in different countries and also ensures that the quality of the drug being manufactured and sold globally is consistent and up to the required standards. The said pharmaceutical product has achieved stupendous success amongst the consumers, doctors, physicians and traders on account of its therapeutic efficacy for past several years worldwide including in India. The statement of global sales and marketing & selling expenses pertaining to INDACATEROL Maleate inhalation powder along with the accompanying inhaler are reproduced herein under for ready reference:

4.5 **STATEMENT OF GLOBAL SALES - MARKETING & SELLING EXPENSES OF INDACATEROL MALEATE (mUSD)**

YEAR	SALES	MARKETING AND SELLING EXPENSES
Jan-Dec 2010	33.0	170.3

Jan-Dec 2011	103.2	356.7
Jan-Dec 2012	133.8	365.1
Jan-Dec 2013	192.2	319.7
Jan-Sep 2014	163.6	118.0

4.6 **STATEMENT OF ANNUAL SALES & MARKETING EXPENSES OF INDACATEROL MALEATE - INDIA**

PERIOD	Readily Available Sales Turnover in INR Thousand	Marketing expenses in INR Thousand
Nov-Dec 2010	4,197	5,396
Jan-Dec 2011	5,677	20,337
Jan-Dec 2012	33,649	4,738
Jan-Dec 2013	32,271	350
Jan-Sep 2014	23,628	-

4.7 The Indian Patent Application was examined for patentability and statutory compliances in accordance with the provisions of The Patents Act, 1970 and corresponding Patent Rules, 2003 by the Controller of Patents.

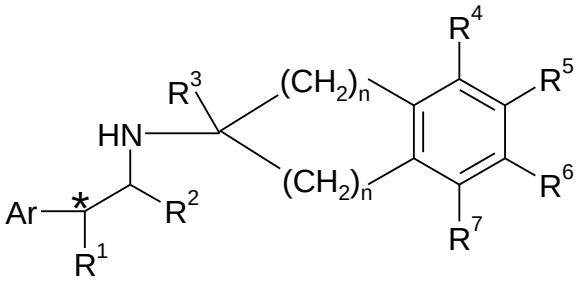
4.8 A statutory period of one year prescribed for filing of such post grant opposition expired on 21st November, 2009. As mentioned above, the suit patent was granted in India as of 5th August, 2008 and its patentability has remained unchallenged till date.

5. One of the arguments advanced on behalf of the plaintiffs is that it is a valid patent. No evidence contrary to its validity has been produced, therefore, the plaintiffs are entitled to protection for their patent and an order of injunction against defendant who is infringing the suit patent. The present remedy is only the efficacious remedy available in law to protect its statutory right of exclusivity granted vide Section 48 of The Patents Act, 1970. And by virtue of monopoly rights granted under the Act for a particular period of time, this court is only has a power to issue an injunction in a suit for infringement under Section 108 of the patent Act. It is submitted that the equivalent patents protecting INDACATEROL and INDACATEROL Maleate have been granted in many countries worldwide and to date they have never been challenged nor invalidated in any jurisdiction on ground of patentability.

6. The suit patent IN 222346 covers INDACATEROL in claims 1 to 4 and 6 to 9 and its maleate salt, namely INDACATEROL Maleate, is covered by claim 9. In addition, pharmaceutical compositions comprising INDACATEROL and INDACATEROL Maleate are covered by claim 10.

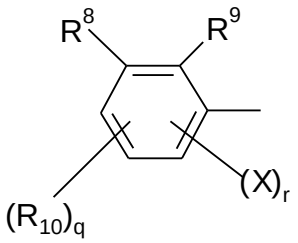
It is alleged in the plaint that as can be noticed from the claims of suit patent IN 222346, they cover a set of compounds described by Formula I wherein groups “R1-R7”, “Ar” and “n” may be chosen from a number of alternatives by substitution as specified. One of such compounds is INDACATEROL.

6.1 INDACATEROL corresponds to a compound of formula I illustrated as under in claim 1 of the suit patent:



I

wherein Ar is a group of formula II illustrated as under:



II

wherein

R1 is hydroxy;

R2 and R3 are each hydrogen;

R4 and R7 are each hydrogen;

R5 and R6 are each ethyl or CH3CH2 (which is a C1-C10-alkyl);

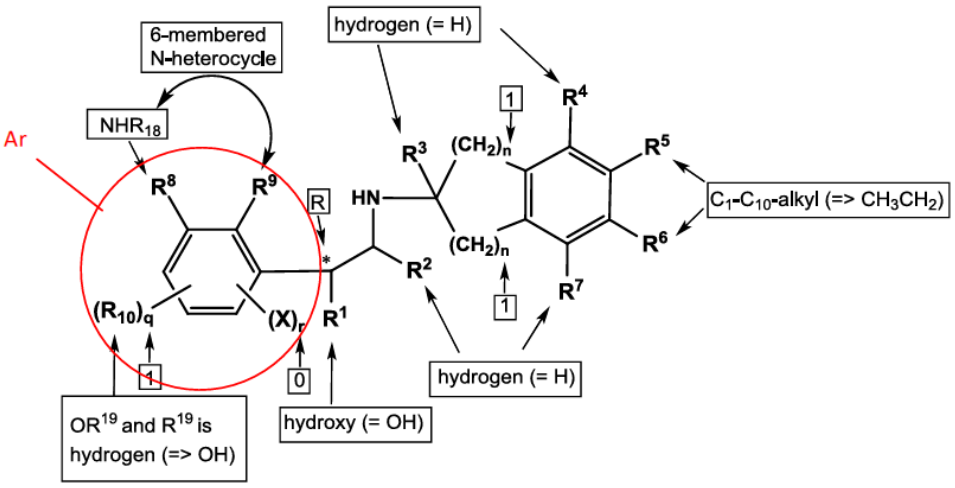
R8 is -NHR18 where -NHR18 and R9 together with the carbon atoms to which they are attached, denote a 6-membered N-heterocycle;

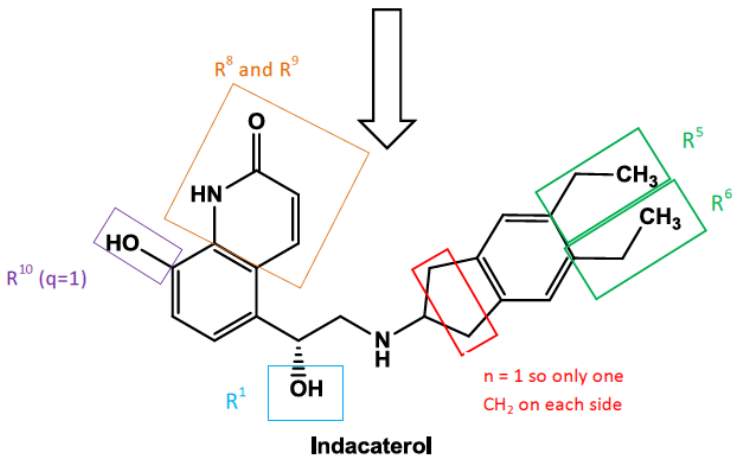
R10 is -OR19 where R19 is hydrogen;

n is 1;

q is 1 and r is zero, the sum of q+r is 1; and

the carbon atom marked with an asterisk* has the R configuration.





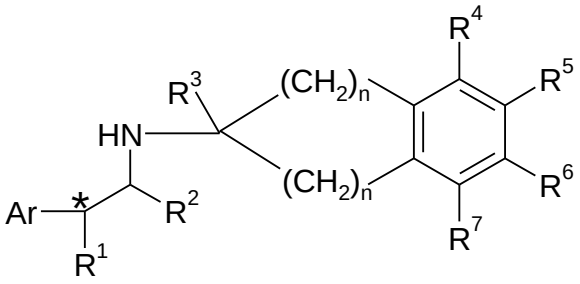
Indacaterol

R^2, R^3, R^4, R^7 are hydrogen so by convention are not shown on this diagram

r is 0, therefore X is absent on this diagram

6.2 INDACATEROL Maleate is specifically covered by claim 9 of the suit patent. The relevant extract from claim 9 pertaining to INDACATEROL Maleate is reproduced as under:

Claim **9. A compound of formula I**



I

(A) ……..

(B) …….

(C) which is a compound selected from (R)-5-[2-(5,6-diethyl-indan-2-ylamino)-1-hydroxy-ethyl]-8-hydroxy-1H-quinolin-2-one maleate.

As will be explained below, this is the chemical name for INDACATEROL. As is evident from the reference to 'maleate' at the end of the chemical name reproduced above, this claim covers the maleate salt of INDACATEROL

6.3. In addition, pharmaceutical compositions comprising INDACATEROL and INDACATEROL Maleate are also covered by claim 10 of the suit patent, which is reproduced below:

> **"Claim 10.** A pharmaceutical composition comprising a compound according to any one of the preceding claims,

optionally together with …….. a pharmaceutically acceptable carrier."

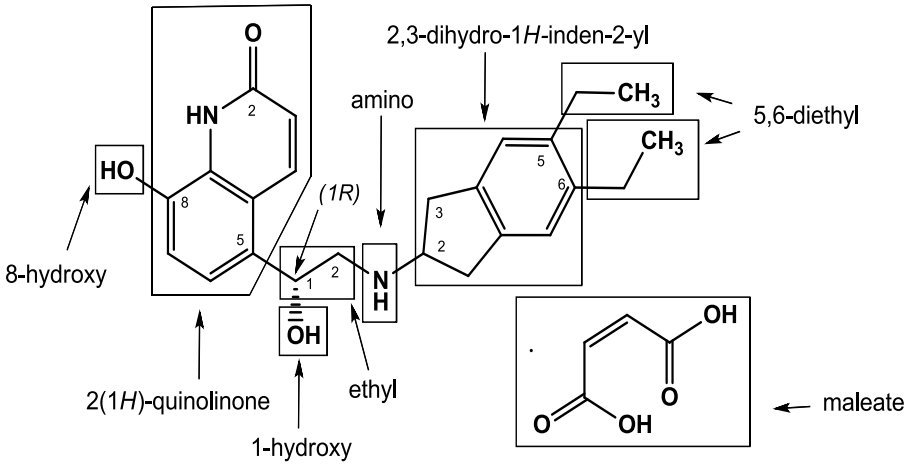
The plaintiffs crave leave of this Hon'ble Court to refer to and rely upon the claims as enlisted in detail in the suit patent document and complete specification placed on record and the contents thereof are not being reproduced and reiterated for the sake of brevity herein and the same may be read as part and parcel of the present plaint.

6.4 The chemical name of INDACATEROL is **"(R)-5-[2-(5,6-diethylindan-2-ylamino)-1-hydroxyethyl]-8-hydroxy-1H-quinolin-2-one**" and that of INDACATEROL Maleate is "**(R)-5-[2-(5,6-diethylindan-2-ylamino)-1-hydroxyethyl]-8-hydroxy-1H-quinolin-2-one maleate"** which is the chemical name used in claim 9 of the suit patent. The said compounds are also known by their chemical names of **"5-[(1R)-2-[(5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino]-1-hydroxyethyl]-8-hydroxy-2(1H)-quinolinone" & "5-[(1R)-2-[(5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino]-1-hydroxyethyl]-8-hydroxy-2(1H)-quinolinone maleate"** respectively. These latter are the CAS names (CAS stands for Chemical Abstract Service which is a division of the American Chemical Society and provides chemical information).

6.5 Both alternatives of chemical names correspond to exactly the same chemical structure. The chemical structure of

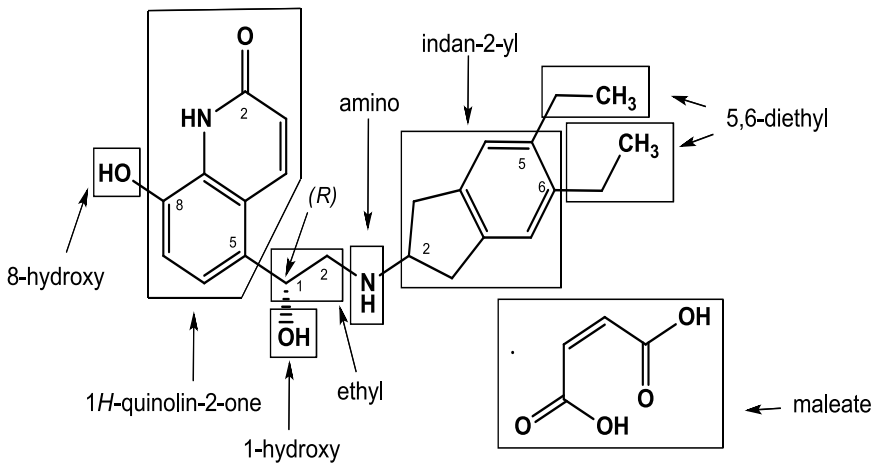
INDACATEROL Maleate with its alternative chemical names is reproduced hereinbelow for ready reference:

I.



5-[*(1R)*-2-[(5,6-diethyl-2,3-dihydro-1*H*-inden-2-yl)amino]-1-hydroxyethyl]-8-hydroxy-2(1*H*)-quinolinone maleate

II.



(R)-5-[2-(5,6-diethylindan-2-ylamino)-1-hydroxyethyl]-8-hydroxy-1*H*-quinolin-2-one maleate

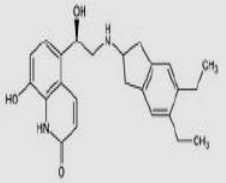
This is submitted that from chemical name INDACATEROL described in "MERCK'S INDEX which is reproduced hereinbelow:

THE MERCK INDEX® Online

Chiron Corp - Europe

ROYAL SOCIETY OF CHEMISTRY

Indacaterol



Monograph ID:	MONO1500004970
Title:	Indacaterol
CAS Registry Number:	312753-06-3
CAS Name:	5-[(1*R*)-2-[(5,6-Diethyl-2,3-dihydro-1*H*-inden-2-yl)amino]-1-hydroxyethyl]-8-hydroxy-2(1*H*)-quinolinone
Additional Names:	(*R*)-5-[2-(5,6-diethylindan-2-ylamino)-1-hydroxyethyl]-8-hydroxy-1*H*-quinolin-2-one
Manufacturer Code:	QAB-149
Molecular Formula:	$C_{24}H_{28}N_2O_3$
Molecular Weight:	392.50
Percent Composition:	C 73.44%, H 7.19%, N 7.14%, O 12.23%
Standard InChI:	InChI=1S/C24H28N2O3/c1-3-14-9-16-11-18(12-17(16)10-15(14)4-2)25-13-22(28)19-5-7-21(27)24-20(19)6-8-23(29)26-24/h5-10,18,22,25,27-28H,3-4,11-13H2,1-2H3,(H,26,29)/t22-/m0/s1
Standard InChIKey:	QZZUEBNBZAPZLX-QFIPXVFZSA-N

7. It is averred in the plaint that plaintiff No.1 is also the proprietor of process patents and patent applications either pertaining to novel process and steps invented for manufacture of INDACATEROL and INDACATEROL Maleate such as IN 210047, IN 230049, IN 262322, IN 230312, 4678/CHENP/2008, and 69681/DELNP/2012, or covering other salts of INDACATEROL or the combination of INDACATEROL or salts thereof with other active ingredients such as 9984/DELNP/08, IN 214320 and IN 256182. The present suit is confined to the

infringement of suit patent IN 222346 which provides protection for the novel and inventive compound INDACATEROL and its salt INDACATEROL Maleate as a compound.

The defendant has yet to file the written statement. The defendant has filed the reply and document along with list of document dated 11th December, 2014.

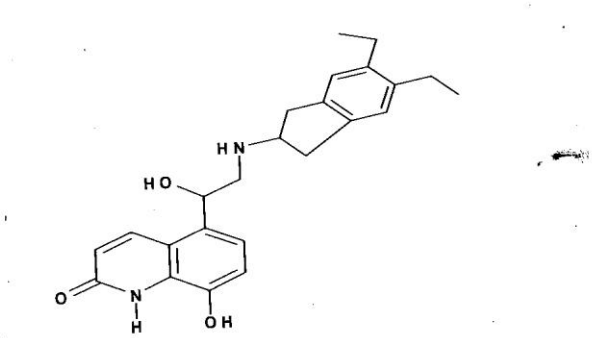
Defendant's Case in Reply

8. The defendant has filed a detailed representation under Section 66 and 92(3) of the Act on 22nd October, 2014, seeking that the Central Government be pleased to revoke the said suit patent IN222346 as well as other patents being IN230049, IN210047, IN230312, IN214320, inter alia, on the reasons that the patented product is not available for patients or doctors to prescribe. The defendant has an expertise in manufacturing respiratory drugs and its products are available at almost one-fifth of the price of Novartis's drug. There being no justification for not making the products in India, the patent rights are liable to be revoked and the defendant be permitted to make the product.

9. In reply to the interim application it is stated by the defendant that the impugned suit patent is liable to be revoked on various grounds under Section 64 of the Act including the grounds that the Plaintiff No.1 has obtained a patent IN222346 for an alleged invention titled "BETA 2-ADRENOCEPTOR AGONISTS". In particular the patent relates to a group of organic compounds as depicted by the below formulae. These

compounds are used as pharmaceuticals, particularly for the treatment of obstructive or inflammatory airways diseases. According to the Patentee, the compounds of formula (I) in free, salt or solvate form, have good beta-adrenoreceptor agonist activity.

The defendant states that claim 1 of the impugned patent is a Markush structure and it encompasses a large number of compounds as depicted by formula I. The defendant is particularly aggrieved by the grant of claim 9, which inter alia, claims a compound, which has the below formula and its INN name Indacaterol, particularly in its salt form. The IUPAC name of Indacaterol is (R)-5-[2-[5, 6-Diethyl-2, 3-dihydro-1H-inden-2-yl)amino]-1-hydroxyethyl]-8-hydroxyquinolin-2(1H)-One.



The defendant being aggrieved by the grant claim 9, vis-a-vis Indacaterol and its salts thereof, of Patent No.IN222346 and seeks the revocation of the said Patent to IN222346.

10. To the extent of the inadequacy of the drug in India has been estimated by the defendant as follows :

a. For one month, one patient will need 1 bottle of 30 capsules per month of Indacaterol which is hereby mentioned as "1 Unit".

b. The number of patients tentatively suffering in India, as mentioned above, is about 1.5 crores. The current population of India is approximately 121 crores. Therefore, approximately 1.23% of Indian population is suffering from COPD.

c. Accordingly, the amount of Indacaterol required is 1.5 crores units per month. Assuming each patient takes the medication for 12 months (which is the standard dosage of the drug), India's requirements will be fulfilled by 1.5 crore x 12 Units per year. The said figure is 18 crores units per year.

d. However, the supply through imports by Novartis is approximately 54 Thousand units per year on an average (as per the Form 27s filed with the Patent Office, which is publically available.)

e. 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%.

It is alleged by the defendant that the 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 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. The same, if compared to the quantity of the drug being imported by the plaintiffs through Lupin Limited (as revealed from the Form 27s filed by the plaintiffs before the Patent Office), the deficiency as calculated above is 99.97%.

11. The case of the defendant in reply is that the plaintiff No. 1 has failed to make the product available to the patient population in India. The imports, if any, by the Plaintiff No. 1, directly or through its licensees. It is submitted that it is impermissible in law for any patentee to register a patent and same to perpetuate a monopoly, without making the patented drug available to the patients, while simultaneously trying to prevent third party from manufacturing and selling the drug for the benefit of patients.

12. It is submitted that COPD is a disease which affects a large section of the Indian population, and is more prevalent among sections that indulge in smoking or are in proximity to smoke. It also affects the semi-urban/rural population in the country, which does not use cooking gas or electric cooking methods and are exposed to biomass fuel.

13. The following articles are referred by the defendant during the course of argument in support of its submission:

a. Article titled *"Chronic Obstructive Pulmonary Disease: Indian Guidelines and the Road Ahead, 2013"*, Parvaiz A. Koul, Lung India 2013; 30; 175-7.

b. "…India contributes a significant and growing percentage of COPD mortality which is estimated to be amongst the highest in the world, i.e. more than 64.7 estimated age standardized death rate per 100,000 amongst both sexes…the national burden is thus estimated to be 14.84 million…"

c. Article titled *"A Review of Population Studies from India To Estimate National Burden of Chronic Obstructive Pulmonary Disease and Its Association With Smoking",* S.K. Jindal, A.N. Aggarwal, D. Gupta, Indian J Chest Dis Allied Sci; 2001; 43: 139-147**.**

"…Total Burden in the year 1996… Considering the overall prevalence rates of COPD of 5 and 2.7% for the male and female patients, the total disease burden was calculated as 8.15 millions and 4.21 millions respectively. Burden of smoking associated COPD was estimated at 6.7 millions in the male population…"

d. Report of the ICMR INSEARCH study titled "*Indian Study on Epidemiology of Asthma, Respiratory Symptoms and Chronic Bronchitis in Adults (INSEARCH)(2012)"*, S.K. Jindal et. al, Int J Tuberc Lung Dis; 16 (9): 1270-1277.

"…A total of 169575 individuals were surveyed at 23 sites across 12 centres. These includes 60764 and 108811 persons residing in respectively 12 urban and 11 rural locations at the time of interview…As per the 2011 census projections, the Indian population aged more than 15 years and less than 35 years is estimated as respectively 845 million and 415 million.

Corresponding to 2.04% population prevalence, nearly 17.23 million people aged more than 15 years have asthma. Similarly, corresponding to 3.58% population prevalence, 14 .84 million people aged more than 35 years have Chronic Bronchitis..."

e. Article titled *"COPD: The Unrecognized Epidemic in India"*, S.K. Jindal, Supplement to JAPI, 2012, Volume 60.

"…An epidemic is defined as a widespread occurrence of a disease in a community at a particular time. It is characterized by a relatively sudden appearance which lasts for over a short period of time. On the other hand, COPD is a chronic, non-communicable disease which poses a continuous burden on health care infrastructure without any sudden increase in the "incidence rate". It is not limited to a shorter time period. Also, it does not present with an acute threat to life in large numbers. Yet it is classified as an "epidemic" largely because the burden which it poses is huge and widespread. Moreover, the burden has become noticeable relatively recently**.** Factually, it still remains unrecognized in the developing countries – whatever data we have from India at present is merely a pointer to the enormous number of patients and an unassessed but huge burden of disease-attributable economic losses, disease morbidity and premature mortality…

…Burden of COPD like that of any other chronic disease, is cumulative and keeps on adding with time. Ironically, the economic burden grows further with an improved survival and newer treatment modalities**.** Undoubtedly however, the losses from loss of DALYs and premature mortality are reduced with improved management…

> …But the total burden of COPD has more than doubled to about 14.84 million in 2011 from about 6.45 million in 1971…
>
> …COPD being a chronic, progressive disease poses a huge economic burden on the patient as well as the health-care systems**.** At individual level, it frequently proves to be financially ruin-some for families with average income…"

14. It is submitted that the exclusive right of a patent, being granted in exercise of a sovereign function, is always meant for the benefit of society and public at large. The purpose of granting patents is to ensure that innovations are disclosed to the public and are used for the benefit of the public.

15. It is averred in the reply that the Court, which exercises powers to revoke a patent, ought to take `working of the patent' into consideration while adjudicating an application for injunction, more so in the light of the fact that the *working* of patents is essential. Working is to be interpreted as per Section 83.

16. In the present case, Plaintiff no. 1 has given no reason whatsoever for the following:

a. Not manufacturing the drug in India by itself;
b. Not manufacturing the drug in India through an assignee or licensee or anyone else;
c. Not importing sufficient quantities of the drug in India;
d. Not making available the drug to the patients at large at affordable prices.

17. The intention of plaintiff No. 1 is to continue imports at a lower quantity at a very high price and perpetuate its monopoly with multiple patents. Plaintiff No. 1 is obviously concerned about the effect of a low priced launch by it in India. Thus the interest of plaintiff No.1 is purely commercial.

18. The Defendant has also moved an application before the Court for the impleadment of the Government as the matter raises questions of huge public importance. Notice on this application has been issued. The reply on behalf of plaintiffs is awaited.

19. The defendant has also raised the point of international position and the importance of access to medicines has been repeatedly reiterated even at the international level i.e. TRIPS agreement itself in Article 7 affirms the importance of Patents being a tool for technological dissemination and technology transfer as well as the **Doha Declaration on the TRIPS Agreement and Public Health** about the obligation of member states to provide adequately for life saving medicines and the GATT negotiations where India had taken his position on working of patents.

20. It is submitted by the defendant that the Constitution of India under Article 21 protects the `Right to life' of its people. This Right to Life enshrined in the Constitution is not merely a monotonous statement but an obligation that no person shall be deprived of his *life of personal liberty except by procedure established by law*. This solemn obligation has been interpreted

by the Supreme Court to include the '**Right to Health**'. The statutory right granted to a patentee under patent law is always to be exercised in a manner which protects preserves and promotes the Constitutional intent to promote the right to life and not in a manner contrary thereto.

21. It is submitted by the defendant that any interpretation of Section 48 and section 83 of the Act has to be in the context of Article 21 of the Constitution and the same cannot be ignored. The case of ***Jeevan Jyoti Health & Welfare Society Versus Union of India & Anr.*** is referred by the defendant.

22. On the issue of balance of convenience, it is stated by the defendant that in the present case the drug of the defendant should not to be injuncted. The same would be available for the patients and with the strength of the Defendant in the respiratory drug segment. It would be made available to the large number of patients in the country. The defendant has launched the same in October 2014, who has made substantial sale of about 12,148 units of the drug.

23. It is suggested by the defendant that the Defendant may be put to terms for depositing of a royalty rate i.e. a percentage of its sales in the court subject to the trial of the suit.

24. The defendant has also referred the decision of Bombay High Court wherein it was held that importation can only constitute working provided sufficient justification is provided. (see Bayer Corporation versus Union of India & Ors, Writ Petition No.1323 Of 2013 (Bombay High Court), para 47 to 49)

Rejoinder to the Reply by the plaintiffs

25. The plaintiffs filed the rejoinder to the reply filed by the defendant. The relevant extract of the rejoinder is mentioned as under:

i) The Defendant in the present case itself relies upon Section 66 and 92(3) of the Act before the Government while filing the representation in October, 2014 to revoke the patent, which is an admission that the suit patent is otherwise valid and infringed by the Defendant. Once a person accedes to a plea that Section 92 of The Patents Act is applicable, it is per se by implicit an admission on its part that it is a valid patent. There cannot be a compulsory licensing without there being a valid patent. So, the very fact that Section 92(3) has been mentioned is sufficient admission in this case on behalf of the Defendant for the purposes of disposal of the injunction application and also an admission that there is an infringement.

ii) It is apparent from the reply that the Defendant believes that the Plaintiffs' patent can be subject to compulsory license under Section 92(3) and thereby admitting the validity thereof, however, it does not make any qualification that reference to Section 92(3) is without prejudice to the plea under Section 64 of The Patents Act. Therefore Section 92(3) as

an admission will operate against the Defendant. In the absence of any specific reservation on the part of the Defendant, it is submitted that the plea under Section 92(3) constitutes admission that a valid patent has otherwise been granted to the Plaintiff No.1. A valid patent alone could be subjected to compulsory license and hence any plea raised herein by the defendant based on Section 64 is liable to be rejected.

It is denied that the quantities imported of the patented drug is negligible and almost 99.9 percent of the patient population does not have access to the drug. Though the Defendant has produced some articles in terms of COPD treatment requirement in India, they require verification and there is no disclosure if they all are INDACATEROL patients. There are several categories of COPD patients as admitted by the Defendant requiring different line of treatment, dosage and drug. Indacaterol is only a treatment for mild and moderate COPD condition patients and not for all categories of COPD patients as alleged. The defendant has deliberately made misleading allegations. In fact, it is also admitted that the Defendant itself is manufacturing and selling COPD drugs and it is beyond comprehension as to why the

Defendant has not been able to fulfill the requirement of COPD patients in India.

iii) It is denied that the manufacture of the drug in India would reduce the price. The price of the drug depends on several factors including the quality, research and development, clinical trials, volume of demand and supply etc. the defendant is well aware of these factors. However, it has deliberately distorted the facts by making unfounded allegations. It is submitted that the Defendant can sell its drug cheaper as it has not invested huge sums in research and development like the Plaintiff and in clinical trials demonstrating the quality and safety of the drug. Instead the Defendant is piggy backing on work carried out by the Plaintiff for its own commercial gain.

iv) The Plaintiffs have fulfilled their requirement, responsibility and obligation under the Patents Act to supply the patented drug according to the demand and the requirement raised on it. Nevertheless, the Plaintiffs are ready and willing to examine and consider if there are any shortfalls and after such verification, would be willing to supply any amount of patented drug to fulfill the requirement as and when it arises. The said requirement has no relationship with the need for a local manufacturer of the drug in

India nor the same is relevant for working of the patent. It is denied that the Plaintiff is making any undue gains or resorting to any unreasonable practices as alleged. The Plaintiff No. 1 has contributed to public health, public interest and right to better quality of life enshrined in Article 21 of the Constitution by disclosing its invention in India by way of the patent application which will go into public domain on expiry of the patent in less than 6 years from today. The Plaintiff has also fulfilled public interest by actually supplying the patent drugs as per the demand in Indian market and are committed to additional supply of product in question if there is a unfulfilled requirement. The defendant has failed to produce the scientific data showing requirement of plaintiff's product to meet the category of COPD patients in India and the short fall of such requirement. However, it cannot be only Plaintiffs responsibility to provide COPD treatment to the entire Indian population and all drug manufacturers including the Defendant share the equal responsibility of fulfilling public interest.

v) Similarly, the Defendant has merely cited certain documents as alleged prior arts without explaining as to how they invalidate the suit patent or which ground of invalidity pleaded under Section 64(1) of

The Patents Act that they pertain to. In absence of such necessary pleading, no further comments can be expected from the Plaintiffs. The Defendant seeks to rely upon such prior art documents and hence are under obligation and have onus to plead as to how reading of such prior arts make the suit patent obvious or renders it invalid. The Defendant has not pleaded any reasons for making such averment. The Defendant cannot rely upon such prior arts by mere filing of the same. The onus on the Defendant remains to explain as to how and in what manner and what combination of reading of which prior arts make the suit patent obvious to the persons skilled in the art. The Plaintiffs have examined all the documents which have been cited as prior arts and state that the same are irrelevant, absent further substantiation of the Defendant. Further, it is pertinent to mention here that the Defendant is guilty of distorting the fact by not making full disclosure that some of the prior arts pleaded by it were subject matter of prior art citations before EPO and USPTO and were suitably distinguished by the Plaintiff in such proceeding leading to grant of patent. The Defendant has deliberately not disclosed such facts before this Court. There is also no pleading as to why if it was

obvious, and so efficacious for COPD treatment none, including the Defendant, came up with the invention before the Plaintiff . There is also no pleading as to if the innovation of the patented drug is so trivial, how and why the Defendant finds it essential to manufacture INDACATEROL as the most efficacious COPD treatment.

vi) The Defendant under the garb of public interest is trying to infringe the suit patent, as it is evident from the fact that despite having made representation to the government under Section 66 and 92 of The Patents Act, the Defendant without even awaiting adjudication thereon by the government proceeded to infringe Plaintiffs' patent immediately.

vii) There is no obligation in law that the Plaintiff must manufacture the patented drug in India. The patent is already being worked. The patented drug is made available to fulfill the requirement of the public and that alone is sufficient. The Plaintiff has already explained in the plaint that it is manufacturing INDACATEROL from its centralized plant in Switzerland so as to ensure that the cost involved in manufacturing and maintaining manufacturing units in different countries is kept to the minimum and the quality of the drug manufactured is consistent and upto the required standards. In any event the

Plaintiff has adduced substantial evidence to show the turnovers for INDACATEROL during the last three years. Although the application for the patent was filed in India in 2001 but it is not necessary that any patent must lead to a commercial product by itself. It is only after sustained years of research and development, clinical trials, relevant test of toxicity, side effects as well as assimilability in the human body and substantial therapeutic quality is established that the patent can be worked "commercially". The plaintiffs allege that the demand is an ever growing phenomena and research on the market forces are being undertaken by the Plaintiffs on a continuous basis. As and when more and more requirements are established depending on market feedback, the Plaintiff is willing to increase its production capacity and fulfill the demand. The market forces determines the demand and supply and pricing accordingly.

viii) The other patents referred to by the Defendant are totally irrelevant for adjudication of issue of infringement of suit patent IN 222346 which is the earliest and the first patent for INDACATEROL and which covers the compound INDACATEROL per se including INDACATEROL Maleate. The Plaintiffs would contest the plea against the other patents as

and when they arise in any proceedings. They surely do not arise in present proceedings. The Plaintiffs submits that it has obtained additional patents which are subject matter of IN 214320, IN 210047, IN 230049 and IN 230312. These patents are additional inventions using INDACATEROL or process to manufacture INDACATEROL and have been granted patents after fulfilling the criteria of novelty and inventive steps. It is submitted that subject matter of all the aforesaid patents are novel and inventive.

ix) The Plaintiffs submit that they are not aware that INDACATEROL is a medication for 1.5 crore patients suffering from COPD as alleged and the Defendant. The total number of patients in India who suffer from COPD has not been accurately assessed.

x) The Defendant might be selling cheaper drugs for COPD but the Plaintiffs drugs are bought for their quality and efficacy. There is no other reason as to why the Defendant is unable to fulfill the requirement of treatment of COPD patients in India. It was denied by the plaintiffs that the import of the Plaintiffs' patent drug is miniscule compared to the actual requirement. It is alleged that there is no data provided by the Defendant as to what is the

requirement of INDACATEROL to treat COPD patients considering that there are different treatments for different categories of patients of COPD. It was added that in any event the requirement of the drug of COPD patients falling in the category which may require the Plaintiffs' drug in question is being met as per the current demand.

xi) The allegation of non-availability of the drug disabling doctors from prescribing the drug in question is concerned, the same is vehemently denied by the plaintiffs. The Plaintiffs have denied the professed efficacy of the drug. It is alleged that that the Defendant has not specified the clinical trial in relation to the respiratory drug manufactured by it. Plaintiffs state it would take all possible steps to provide and meet the requirement of drug, if there is a unfulfilled demand. The need as posed by the Defendant is inaccurate, with vested interest having no credence. All patients of COPD cannot be classified as a class to whom a particular drug is to be administered. It is submitted that the Plaintiffs' product in question is monotherapy suitable only for mild to moderate COPD patients. It is submitted that in India, by the time patient of COPD is diagnosed, he is already in the advanced stage of

disease hence rendering him/her ineligible for monotherapy.

xii) It is submitted by the plaintiff that invoking Article 21 of the Constitution by the Defendant is wholly misconceived and untenable. It is submitted that the Plaintiffs respect the Indian Constitution. The Plaintiffs submit that right to life is recognized by the International Covenant of Civil & Political Rights, 1946 as well as the European Convention of Human Rights and is fully alive to the sanctity which is to be accorded to right to life and dignity. Nevertheless, it is reiterated that the Plaintiffs, as patentee, is conscious of its responsibility towards supplying drugs to the public in India.

xiii) It is denied that INDACATEROL is not available either in government hospitals or chemist shops.

xiv) It is alleged in the rejoinder that there is no requirement in law that the patented drug must be manufactured in India. In any event the requirement of the drug of COPD patients requiring Plaintiffs' drug is being met as per the current demand. It is denied that the sale of patented drug in India by import is not adequate as the patent is already being worked in India. Still the Plaintiff No.1 is open to meet any unfulfilled demand of INDACATEROL in India provided there is such genuine demand and

unfulfilled requirement. It is the Defendant which is creating a false ground to commercialise INDACATEROL for its own gain which is condemnable and ought to be rejected. It is alleged that on one hand the Defendant claims to be the market leader in relation to drugs for respiratory treatment and on the other hand it maintains that the drugs manufactured by it and other drug manufacturers are not able to fulfill the demand of COPD patients. The Plaintiffs submit that they would increase the supply and are capable of increasing the import to whatever extent required to meet such demand provided it receives such feed back and demand from the market.

xv) It is alleged that the defendant has failed to produce the scientific data showing requirement of plaintiff's product to meet the category of COPD patients in India and the short fall of such requirement. However, it cannot be only Plaintiffs responsibility to provide COPD treatment to the entire Indian population and all drug manufacturers including the Defendant share the equal responsibility of fulfilling public interest.

xvi) With regard to reference to paragraph 11 and Article 7 of TRIPS agreement is concerned, it is submitted that the disclosure of the invention by the Plaintiffs

by way of the patent application and supply of patented drugs to public at large in India is sufficient compliance of Article 7 as the same has led to promotion of technological innovation and dissemination of technology. The Plaintiff welcomes the Article 7 of the TRIPS Agreement. In fact, it is refreshing to know that the Defendant too wishes to honour the TRIPS Agreement.

xvii) As far as the allegations of the Plaintiffs regarding additional patents or abandoned patents are concerned, pertaining to INDACATEROL, it is submitted that it is only the suit patent IN 222346 which pertains to INDACATEROL including INDACATEROL Maleate, the new chemical entity and the basic compound.

xviii) All the grounds pleaded under Section 64(1) of the Act are denied. It is alleged that the grounds pleaded are basically reproduction of the statutory provisions. The Defendant has merely cited certain documents as alleged prior arts without explaining as to how they invalidate the suit patent or which ground of invalidity pleaded under Section 64(1) of the Act that they pertain to.

xix) The other patents referred to by the Defendant are novel and innovative processes to manufacture INDACATEROL or an intermediate discovered

during said process or an inventive combination or formulation using INDACATEROL. Each one of such patents have been granted on fulfillment of the patentability criteria of novelty, inventiveness and industrial application. These patents are not for compound INDACATEROL, the active ingredient and new chemical entity.

xx) The Defendant has several products in the market and is one of the market leaders in this field. The Defendant is free to sell other products. It is therefore submitted that there is no prejudice that the Defendant will suffer in case the injunction is granted to the Plaintiffs. So far as the issue of public interest raised by the Defendant is concerned, the Plaintiffs assure this Court to take all such necessary steps which may be required to meet the additional supply as and when there will be a unfulfilled demand. It is submitted that the requirement for the drug by COPD patients is being met as per the current demand.

xxi) It is mentioned here that the Defendant is guilty of concealment of facts, non-disclosure and deliberate suppression of material information from this Court that the Defendant itself has filed several patent applications for formulation containing patented compound INDACATEROL, however, having failed

to overcome the inventive step abandoned the few. Such non-disclosure is deliberate and with the sole intent to mislead this Court. Such non-disclosure warrants that the Defendant has approached this Court with unclean hands and ought to be injuncted on this ground alone.

xxii) Such applications of the Defendant are as under:

- **WO 2008/10128. First priority 19.2.2007**. Indian Patent Application no. 314/MUM/2007 (application withdrawn) and 1541/MUMNP/2009 (application abandoned U/S 21(1)). This patent family is/was intending to cover a pharmaceutical combination comprising (a) a combination of two or more bronchodilators; or (b) a combination of at least one bronchodilator in combination with at least one corticosteroid. INDACATEROL is specifically mentioned in the patent application specification and claims as a bronchodilator.

- **WO 2012/007729. First priority 16.7.2010.** Indian Patent Application no. 321/MUMNP/2013 (Application Awaiting Examination) and 2051/MUM/2010 (Deemed to be Withdrawn U/S 11B(4)). This patent family is/was intending to cover a pharmaceutical composition comprising R(+) budesonide and one or more bronchodilators such as indacaterol (among others beta2-agonists).

- **WO 2012/049444. First priority 12.10.2010.** Indian Patent Application no. 844/MUMNP/2013 (Application Awaiting Examination), 2105/MUM/2010 (Application Awaiting Examination), and 2847/MUM/2010 (Deemed to be Withdrawn U/S 11B(4)). This patent family is/was intending to cover a pharmaceutical composition comprising INDACATEROL or formoterol in

combination with a corticosteroid selected from fluticasone and ciclesonide, and, optionally, one or more pharmaceutically acceptable excipients.

- **WO 2012/110770. First priority 17.2.2011.** Indian Patent Application no. 446/MUM/2011 (Request for examination not filed) and 1687/MUMNP/2013 (Request for examination not filed). This patent family is/was intending to cover a pharmaceutical composition comprising glycopyrrolate in combination with a beta2-agonist such as INDACATEROL (among others beta2-agonists), and optionally one or more corticosteroid.

- **WO 2014/064410. First priority 23.10.2012.** Indian Patent Application no. 3092/MUM/2012 (request for examination not filed yet). This patent application intends to cover a pharmaceutical composition comprising tiotropium, a hydrofluoroalkane (HFA), and optionally one or more pharmaceutical acceptable excipients, and this composition may optionally also comprise one or more active agents such as INDACATEROL.

xxiii) The Defendant has huge business interest in the patented compound INDACATEROL, which led to filing of several patent applications. However, having failed to overcome the hurdle of establishing of inventive step, abandoned some of the applications and filed the representation before DIPP for its commercial interest under the garb of public interest and public need. This Court ought to take a serious note of conduct of the Defendant of such non-disclosure and the intent behind raising

such frivolous plea of public interest and misusing the forum for its personal business interest.

26. Both the parties have addressed their submissions. Mr.Gopal Subramanium, learned senior counsel, has argued on behalf of the plaintiffs. Mr.P.Chidambaram, learned senior counsel, has argued on behalf of the defendant.

27. Mr.Gopal Subramanium, learned senior counsel appearing on behalf of the plaintiffs, has referred pleadings and documents. His main submissions are outlined as under:

i) His first submission is that it took plaintiff No.1 well over 10 years to develop, launch and commercialize INDACATEROL in the market internationally as well as in India.

ii) His second submission is that the Controller of Patent was satisfied with the novelty, inventiveness and industrial application of the compounds claimed. After full security and strict examination Controller of Patent has granted Indian Patent No. 222346 (Suit Patent) to the Plaintiff No.1. It has not been challenged by anyone. It is an old registration. The plaintiff No.1 has got the exclusive rights to use the patent. No person has a right to infringe the same. The defendant in the present case in order to earn easy profit has infringed the suit patent knowingly that it is exclusive ownership of defendant No.1.

iii) The third submission of Mr.Subramanium, learned senior counsel, is that the defendant has failed to establish credible defence. There is no material placed on record by the defendant about the invalidity of the suit patent. Therefore, in view of the monopoly rights granted under Section 48 of the Act for a particular period, the Court is empowered to issue the injunction in a suit for infringement under Section 108 of the Act which is only the appropriate remedy under the Act.

iv) The next submission of Mr.Subramanium is that there is no obligation in law that the plaintiff must manufacture the patented drug in India which is already being marketed by Lupin and the same is easily available. He says that the patent in question is already working in India as patients are getting the said medicine. He referred the affidavit of Mr.Kuldeep K Wakhloo in this regard. He submits that further research of the patented drug is continuing and assured the Court that as and when market forces will demand higher supply, his client would do the needful without any delay and the price would also be reworked in accordance with the market demand.

v) He gave the suggestion that in case of any doubt, his clients are ready to set up a committee to

enquire into the concerns raised by the defendant who would submit its report within the time fixed by the Court about the availability of stock and if it is found that the drug in question is not available to the concerned patients, the plaintiffs shall take immediate steps to meet the demand for COPD treatment. But under the shelter of conditions provided under Section 83 of the Act, the defendant should not be permitted to manufacture the drug under the suit patent in order to infringe the same. Once it is allowed, many other manufacturers would start infringing the suit patent. The suit patent would be in public domain.

vi) The next submission of learned senior counsel is that the defendant has in fact admitted in the reply as well as representation made before the Government that the patented drug is an effective and it is convenient to the patients and when administered in combination with other drug, the same has proven to be quite beneficial and in fact in the reply, the defendant has suggested and agreed to deposit royalty at a rate i.e. a percentage of its sale. These admissions of the defendant prima facie establish that it is a valid patent and the product manufactured by the defendant is infringing one.

vii) He suggests that in case the defendant is more concerned about the public interest, the defendant may import the plaintiffs' drug of the suit patent and sell in India for which his client is prepared for such arrangement.

28. By making the above said submissions, Mr.Subramanium, learned senior counsel, urged that the plaintiffs have a strong case for grant of interim order and it is a valid patent. The balance of convenience lies in favour of the plaintiffs and against the defendant. Therefore, the plaintiffs are entitled for an injunction as prayed for.

29. Mr.P. Chidambaram, learned senior counsel appearing on behalf of the defendant, has made his submission. The main issues raised by him are outlined as under:

i) First submission of Mr.P. Chidambaram, learned senior counsel appearing on behalf of the defendant is that the reasonable requirement of the public with respect to the patented invention have not been satisfied. Patented drug is not being manufactured on commercial scale in India. It is a non-working patent in India. The demand of few patients is met by the plaintiffs by way of importation from abroad. As there is a hindrance since the demand is not met by the plaintiffs to an adequate extent, the commercial activities in India are prejudiced of an existing trade and industries. The patented drug is

not available to the public at a reasonable price. Therefore, the defendant is entitled to trade in India for the purpose of development of commercial activities. He says that two recent surveys conducted by an independent investigation agency would show that the plea raised by the defendant is tenable.

ii) His second submission is that the defendant has filed on record several articles which establish that COPD has assumed epidemic proportion in India. These articles have been in public domain since the last many years. Being a patentee, it is the duty and obligation of plaintiff No.1 to make the drug available to the ever increasing patients in India. The statutory rights under the Act would never be made subservient to the interest of the public in the cases of life threatening disease. As the patentee has failed to take any step, the public interest should prevail, and an injunction should not be granted and the defendant is entitled to manufacture the drug.

iii) Third submission of Mr.Chidambaram, learned senior counsel, is that the plaintiff No.1 is merely holding the patent of the said drug and but the suit patent is not being worked in India. Section 48 of the Patent Act, 1970 does not help the case of the plaintiffs as the opening lines of the Section 48

stipulates that the same is *"subject to other provisions of the Act"*. Thus, the right of a patentee to prevent others from manufacturing or offering for sale a patented drug is subject to other provisions of the Act. Section 83 is the relevant provisions under the Patent Act which deals with "working" of a patent. The principles laid down in Section 83 would definitely apply in the cases of infringement. It is not merely meant for adjudicating the application of compulsory licensing.

iv) Fourth submission of Mr.P. Chidambaram, learned senior counsel, is that even there is deficiency in availability. He has referred to the figures given by plaintiff No. 1. He refers the number of units imported along with an analysis of the deficiency in availability. The said drug is only imported into India through Lupin Limited, who allegedly is the licensee of the Plaintiffs.

His submission is that the sales are negligible. As per the IMS data for the year 2012, as against the total quantity of importation of 53144 units only 5676 units were sold in the market which is almost 10% of the number of units imported. In the year 2013 as against the total import of 53865 only 5655 units are sold which is again approximately 10%. It is thus clear that the quantity imported is very meagre and

is not commercially sold. Thus, it is apparent that suit patent is no working. Even the quantity being imported and sold is on high prices. The price comparison of the products of Plaintiff no. 1 and the Defendant's drug is tabulated herein below:-

Brand	**Company**	**Strength**	**MRP per 10 caps**
ONBREZ	Lupine Limited	150 mcg	Rs.677.00 [420% more expensive than the price at which the drug is being sold by the Defendant]
UNIBREZ/ INDAFLO	Cipla Limited	150 mcg	Rs.130.00

v) His next argument is that public interest plays an important role in grant of an interim injunction. He says that even the plaintiffs are not aware of the data relating to the patients afflicted with COPD. The patentee in the present case should not to be allowed to perpetuate a monopoly at the cost of the entire society. The Plaintiffs have failed in their duty to make drug available to the people of this country. The data referred by the Defendant is backed up by the articles which are placed on record. A mere denial by saying that the data ***"needs verification"*** would not serve the requirement of concerned

patients. The statutory rights do not help in favour of a patentee, who has failed to do his obligation. The case law relied upon by it on the issue of non-use of patented drug in India where the injunction was refused on non-working are as follows:

i. Franz Xaver Huemer versus New Yash Engineers, 1996 PTC (16) DB,para 15, 28, 29

ii. Glaverbel S.A. versus Dave Rose and Ors., 2010 (43) PTC 630 (Del), para 83

iii. Sandeep Jaidka versus Mukesh Mittal &Anr., 2014 (59) PTC 234 (Del), para 36

Learned senior counsel has also referred the decisions in support of his submissions:

(i) In the case of **Bayer Corporation versus Union of India &Ors, Writ Petition No.1323 Of 2013 (Bombay High Court)**, the following observation was made:

"…Therefore even earlier, the requirement was failure to manufacture in India to an adequate extent. Be that as it may, whether the invention is being worked in territory of India has to be looked at through the prism of Section 83 of the Act which contains the legislative guidelines to govern the meaning of the words 'worked in the territory of India'. The guidelines viz. Section 83 of the Act in particular states that the patent is not granted so as to enable

the patent holder to enjoy a monopoly with respect to the importation of the patented article. Thus it would presuppose that some efforts to manufacture in India should also be made by the patent holder. This is further supported by the other considerations set out in Section 83 of the Act to be applied in construing 'worked in territory of India'. Section 83(c) of the Act provides that there must be transfer of technological knowledge to the mutual advantage of the producers and users of the patented article……However, the patent holder would nevertheless have to satisfy the authorities under the Act as to why the patented invention was not being manufactured in India keeping in view Section 83 of the Act. This could be for diverse reasons but it would be for the patent holder to establish those reasons which makes it impossible/ prohibitive for it to manufacture the patented drug in India…". *(emphasis supplied)*

(ii) The case law of **Bard Peripheral Vascular, inc. and Ors. v. W.L. Gore & Associates, INC.**, Appeal from the United States District Court for the District of Arizona in case no. 03-CV-0597, is relied upon by the defendant:

"The district court denied Bard's request for a permanent injunction finding that it was in the public interest to allow competition in the medical device arena, but in lieu thereof granted Bard an ongoing royalty to

> compensate for Gore's future infringement....The court set a 12.5% to 20% royalty rate on Gore's grafts depending on the different types of graft. License, slip op. at 15–16.
>
> The award of an ongoing royalty instead of a permanent injunction to compensate for future infringement is appropriate in some cases….**Because of the public interest as the court here determined, "the district court may wish to allow the parties to negotiate a license amongst themselves regarding future use of a patented invention before imposing an ongoing royalty." But if the parties cannot reach agreement, "the district court could step in to assess a reasonable royalty in light of the ongoing infringement**."

30. In reply to concealments it is submitted by the defendant that the Plaintiffs have sought to aver that "That the Defendant itself has filed several patent applications for formulations containing the patented compound Indacaterol... and such non-disclosure is deliberate and with the intent to mislead the Court." The said contention is not correct as the said applications are patents for combinations/compositions of various drugs that may or may not include Indacaterol. These are formulations and process patents applied for to enable export of the product. These do not in any manner prevent the Defendant to challenge the validity of the suit patent.

31. By making the above said submissions, Mr.Chidambaram urged that the relief sought by the plaintiffs is liable to be rejected by dismissing the interim application. However, the learned senior counsel on behalf of the defendant has fairly stated that "**if this Court would come to the finding that it is a valid patent then the case of infringement is made out**".

32. I have considered the plaint and the documents filed therewith, the written submissions filed by both the parties and the submissions advanced by the learned counsel for the parties at the bar. I shall now proceed to discuss the various aspects which fall for consideration in the present matter.

INFRINGEMENT AND VALIDITY OF PATENT

33. The suit patent no. IN 222346 was applied by Plaintiff No.1 as international application being PCT No. PCT/EP2000/005058 as of 02.06.2000 claiming priority from UK 9913083.3 dated 04.06.1999. The said international application was filed in India on 28.11.2001. It was published on 22.06.2007. No pre-grant opposition was filed by any one of public under Section 25(1) of the Act. The patent was granted on 05.08.2008. The grant of patent was published on 21.11.2008. No post grant opposition was filed by anyone. No revocation has been filed for this patent till date. The patent is valid till 02.06.2020. It is in Maleate form is disclosed in Example 21(b) prepared by synthesis of intermediate disclosed in Example 21(a) of the suit patent. It is claimed as one of the compounds in class of compounds claimed in claim 1 of the suit

patent IN 222346. The said INDACATEROL Maleate is claimed in claim 9 of the suit patent. The chemical formula and chemical structure of INDACATEROL and INDACATEROL Maleate is already reproduced in earlier part of my order. INDACATEROL is also enlisted by its chemical formula and chemical structure in "Merck Index"

34. It is true that an obligation is imposed on a patentee to work the patent in India on a commercial scale and to fullest extent. The patent may be worked by the patentee himself or through licensees. Failure to fulfil this obligation will entail in the granting of compulsory licences or the revocation of the patent itself.

35. It is the admitted position that the drug INDACATEROL was first approved by the European Medicine Agency only in 2009 and by the US Food and Drug Administration in 2011. However, the Controller of Patents granted the patent IN 222346 on 05.08.2008. After obtaining requisite license and marketing arrangements and considering the quality which was being made in the manufacturing facilities in Switzerland from where the drug is being imported in India is being sold since 2010.

36. Patent rights are often considered as highest in the category of monopoly rights in the regime of Intellectual Property. This is due to the reason that patent right is absolute monopoly position where a patentee can prevent any person misusing the patent from manufacturing the project or arrive at

the product through a process which is subject matter of patent. Thus, patentee being a right holder which is a privilege granted by a Sovereign State can enjoy this position of monopoly of manufacturing or making the process for a limited period of time to the exclusion of others. In fact patent infringement is and always has been a form of tort actionable by the patentee or if applicable by his exclusive licensee. The right of patent is statutory in nature and the said right stems from the Statute.

37. Once the said statutory rights are granted, the courts are normally faced with the situation where a patentee seeks prohibitory orders in the interim so that monopoly rights granted to him are given due acceptance are recognized by the courts. Therefore, the question which arises as to what are the principles normally in the cases relating to patent infringement is the grant of temporary or permanent injunction.

38. The patent law in India is governed by Patents Act 1970 as amended in the year 2005. What constitutes infringement of a patent is not denied in the Act. Thus, one has to gather the meaning of infringement from the scope of the monopoly rights conferred on the patentee for infringement is the violation of those rights. Section 48 confers on the patentee, his agents and licensees the exclusive rights to make, use, exercise or distribute invention in India. The rights of the patentee are infringed if anyone makes and supplies or commercially uses and the patentee may be granted interim order, subject to the condition if the patent is valid. It is not incumbent upon the

plaintiff in case of infringement to show that the plaintiff has suffered commercial loss.

39. Lord Denning M.R. in his famous speech in the case of ***Hubbard and Another v Vosper and Another*** **(1972)1 All ER 1023 at 1029**, had observed in considering whether the grant of interlocutory injunction, the right course for a Judge to look at the whole case and form a holistic view of the matter. In the words of Lord Denning, it was observed thus:-

> ***"In considering whether to grant an interlocutory injunction, the right course for a judge is to look at the whole case. He must have regard not only to the strength of the claim but also to the strength of the defence, and then decide what is best to be done. Sometimes it is best to grant an injunction so as to maintain the status quo until the trial. At other times it is best not to impose a restraint on the defendant but leave him free to go ahead. For instance, in Frazer v Evans (1969)1 All ER 8, although the plaintiff owned the copyright, we did not grant an injunction, because the defendant might have a defence of fair dealing. The remedy by interlocutory injunction is so useful that it should be kept flexible and discretionary. It must not be made the subject of strict rules".***

40. The authority namely **Kerr on Law and Practice of Injunction**, **6th Edition on page 320** discusses some principles which may act as guiding factors for the grant of injunction in patent cases. The said factors are stated as follows:-

> ***"If one clear instance of infringement or a wrong prima facie case of infringement is***

made out and the plaintiff has not been guilty of laches, the court will generally grant an interlocutory injunction in following cases: (1) when the validity of the patent has already been established in a previous action, (2) when the patent is of old standing and the enjoyment under it has been uninterrupted (3) when the validity of the patent is not in issue and notwithstanding that the defendant offers to keep an account."

41. In the case of ***F. Hoffmann-La Roche Ltd vs Cipla Ltd., Mumbai Central*** **decided *on 24 April, 2009***, Division Bench of Delhi High Court speaking through Hon'ble Justice S. Murlidhar has observed that the court has to see the tenability and the credible nature of defence while deciding the grant or non-grant of injunction. If the defendant's case is found to be tenable and there are serious questions as to validity to be tried in the suit, then the interim injunction in the case may not be granted.

42. From the above, it is clear that if there is a strong *prima facie* case and the validity is not further seriously questioned, then there is a clear way out to grant injunction.

43. It is obvious and settled law that although the patent rights are statutory in nature and the said rights are governed by the rights granted by the certificate under the Act, still the comparative prejudice has to be weighed on the basis of ground realities.

44. It is also well settled law that if patent has not been sufficiently exploited in India and there is no user of the said patent in commercially viable form in India, the court may tilt the

discretion in the interim stage in favour of the defendant. [See the case of ***Franz Xaver Huema v Yash Engineers*** *AIR 1997 Del 79 (DB) at 82 para 12* and also the case of ***Manicka Thevar v Star Plough Works*** *AIR 1965 Mad 327****, Sandeep Jaidka vs. Mukesh Mittal & Anr.***, (2014 (59) PTC 234 (Del.) and ***Glaverbel S.A. vs. Dave Rose and Ors.***, 2010 (43) PTC 630 (Del.)

45. The facts, which are not denied by the defendant, are given as under:

a) **The defendant has not denied the factual position that the plaintiff No.1 is holding the registration of patent in respect of drug in question. The said patent is subsisting on the Register.**

b) **The defendant has launched the same on 24th October, 2014. It was suggested by the defendant in its reply that the defendant be put to terms for depositing of royalty at a rate i.e. a percentage of its sale.**

c) **It is admitted by the defendant that COPD is a disease which cannot be cured. The treatment is symptomatic and long drawn. In many cases, the medicines have to be taken for the entire life of the patient. The existing drugs, *Salmeterol* and *Formaterol* which are available combinations, are administered twice a day on long term basis and the same is not convenient for patients as compared to**

Indacaterol (which is subject matter of the suit patent). Another medicine which is used for the management of COPD is *Tiotropium* and is relatively slow in the onset of action. The patients are in dire need of Indacaterol, which is available in most countries of the world. However, Plaintiff no. 1, for the last six years has not taken any steps to make Indacaterol available to patients in India. The current forms of treatment that are being used in India are inferior when compared to Indacaterol.

d) In fact the Defendant admits the Plaintiffs' INDACATEROL to be the most preferred choice of most physicians as compared to the Defendant's COPD drugs.

e) In view of above admissions, it establishes about the efficacy and inventiveness of the suit patent.

f) The Defendant also admits in the representation made by it before DIPP that the Plaintiffs drug is an efficacious drug, the relevant extract is reproduced hereinbelow for ready reference:

> **"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 re currently indicated for the treatment of COPD."***

In view of aforesaid reasons and admission made, it is apparently evident that the Defendant itself has acknowledged the efficacy and inventive steps of the suit patent.

46. The defendant in its representation filed on 22nd October, 2014 under Section 66 and 92(3) of the Act petition before DIPP has acknowledged the efficacy of the Defendant's drug namely INDACATEROL as preferred choice of physicians which is an acknowledgement of high degree of novelty and inventiveness of the patented compound. Rather in the reply to the interim application, the same was admitted. In reply, the offer was also made by the defendant to pay the royalty to the plaintiff.

47. In order to challenge the patent at this stage, the defendant has filed document in order to show prior arts on record as per details mentioned below :

a. Yoshizaki et al; "*Sympathomimetic Amines having a Carbostyril Nucleus*"; Journal of Medicinal Chemistry; 1976, Vol.19, No. 9; pp 1138-1141
b. US4223137 published on September 16, 1980
c. WO93/18007 published on September 16, 1993
d. Solomons et al; "*2-aminoindans of pharmacological interest*"; Journal of Medicinal Chemistry; 1973, Vol.16, No. 12; pp 1330-1333
e. Levin, B.E. Graham, and H.G.Kolloff, *J. Org. Chem,* 9, 380 (1944)

f. The 1990 Lilly Prize Lecture by David Jack, **"**A way of looking at agonism and antagonism: Lessons from salbutamol, salmeterol and other ~-adrenoceptor agonists" *Br. J clin. Pharmac.* (1991),31,501-514

g. US4026897 published on May 31, 1977

h. US4579854 published on April 1, 1986

i. A book by Graham Patrick, Introduction to Medicinal Chemistry Graham Patrick, published in 1995

j. US5190975 published on March 02, 1993

k. EP0589037 published on March 30, 1994

l. JP63005063A published on January 11, 1988

m. US5891896 published on April 6. 1999

n. EP321175A1 published on June 21, 1989

48. It is settled law that the allegation to challenge the suit patent must be specifically pleaded. The defendant must deliver the particulars of objection on every ground on which its validity is challenged and must include such particulars which will clearly define every issue. It is the admitted position that the defendant's packaging is showing INDACATEROL Maleate as active ingredient.

Learned senior counsel has merely read over the grounds raised in the reply of invalidity of the patent. He has not explained the particulars to show as to how the said documents/prior patents constitutes prior art for the purpose of attaching the suit patent. No arguments were addressed on the

aspect of how the suit patent is prior published from the date of priority date and what was already known and the suit patent is nothing than merely a workshop improvement and it involved no research and skill and it involved no novelty. Even prima facie it is not established that the suit patent lacked novelty, inventive steps and it is prior published by virtue of documents filed in order to show prior art. In fact merely the averment is made in the reply but nothing has been addressed during the course of hearing of the present application.

49. The plaintiffs in their rejoinder have raised the objection that the prior art is not explained by the defendant, still the plaintiffs have chosen to distinguish them. The plaintiffs have given the details of distinction between the suit patent and other patents in rejoinder which would show the difference from the suit compound IN 222346. The same are produced herein below:

Patent Number	Subject matter of invention	Difference in inventive step from the basic compound patent IN 222346
214320	Combinations of Indacaterol (QAB149) with corticosteroid (budenoside/fluticasone propionate/mometasone furoate) in the treatment of an inflammatory or	-combination of Indacaterol with corticosteroid in specific molar ratios (100:1 to 1:300).

	obstructive airways disease. -use of such a combination reduces or eliminates the need for treatment with short acting rescue medicaments like salbutamol or terbutaline.	-No specific molar ratios for such a combination has been disclosed in the suit patent
Patent Number	Subject matter of invention	Difference in inventive step from the basic compound patent IN 222346
210047 (Process patent)	This patent covers some very initial steps (7 steps) of the synthesis of Indacaterol maleate. Specifically, it covers a process for preparing intermediate V7a (5,6 –diethyl -2,3—dihydro-1H-inden-2-amine-referred as Formula VIII in the specification) starting	-such a process for preparation of intermediate V7a was not disclosed in the suit patent. -Different intermediates were used for preparation of

	from starting material V7h: V7h à V7f à V7e à V7d à V7c à V7b à à V7a	Indacaterol
Patent Number	Subject matter of invention	Difference in inventive step from the basic compound patent IN 222346
230049 (Process patent)	This Indian patent covers some very initial steps (4 steps) of the synthesis of Indacaterol maleate. Specifically, it covers a process for preparing intermediate E5 (5-[(Haloacetyl)-8-(substituted oxy)-(1H)-Quinolin-2-ones] starting from starting material E1 [(8-hydroxy-(1H)-quinolin-2-one]: E1 à à E3 à E4 à E5	-such a process for preparation of intermediate E5 was not disclosed in the suit patent. -Different intermediates were used

	-This process provides intermediate E5 (for eg. (5-[(alpha-chloroacetyl)-8-(benzyloxy)-(1H)-Quinolin-2-one] in high selectivity and yield.	
Patent Number	Subject matter of invention	Difference in disclosure made in the basic compound patent IN 222346
230312 (Process patent)	This patent covers some last steps (5 steps) of the synthesis of Indacaterol maleate. Specifically, it covers a process for preparing Indacaterol maleate starting from intermediates E7 and V7a: E7 + V7a à [E8] à [E9] à	-different process of preparation of Indacaterol maleate has been disclosed in Example 21 of IN 222346 (suit patent)

	E9 à E10 à E12 (indacaterol maleate) -This relates to a process for preparing Indacaterol maleate without isolating the free base thereof which is unstable in organic solvents. -this process is useful for large scale production, which provides salts in high enantiomeric purity and high yield.	

50. It is denied by the plaintiffs that the coverage of suit patent IN 222346 and the abovementioned patents is same. It is submitted that each of the subject matters covered by the abovementioned patents are distinct and independent innovations entitled to patent protection. The plea raised by the Defendant is not correct. The above mentioned patents do NOT extend a monopoly on INDACATEROL, but protect just one of many possible ways the produce INDACATEROL or to formulate it with other compounds. Any allegation of evergreening by the Defendant at this interim stage is without

merit. All pleas made by the Defendants in this paragraph with respect to lack of inventive step, obviousness, lack of working of drug are misconceived and hence denied. The patented drug is imported to India through Plaintiff No.2 and is co-marketed through Lupin.

51. In the said attendant circumstances, wherein the prior arts are unexplained and the defendant is taking inconsistent position and also goes on to state that the product under patent which is INDACATEROL Maleate is highly efficacious in curing the COPD and thus desirable by the defendant when the defendant is itself making the other drugs for curing COPD which according to the defendant's own saying are not adequate (which stand is required to be tested before the relevant forum.), it can be said that the plaintiff is able to establish a case of prima facie valid patent on record. The said alleged prior arts which the defendant is duty bound to explain as it is the defendant who has urged the case of prior arts cannot be said to be prior arts in real sense of the term due to the defendants inability to explain the same properly as to how the same leads to workshop result or anticipated piece of art and further taking the position that the products under the patent is highly efficacious.

From the above said reasons it appears that no serious challenge is made and addressed before Court of prior art. Therefore, the submission of the defendant has no force at present.

This is due to the reason that once the distinction in the properties of the patented compound coupled will high level of the efficacy would come into play, then for prima facie purposes the argument of the workshop improvement and section 3 (d) will be withered away due to the reason that the efficacious and distinction in properties would take away the plea of evergreening or derivative of known compound. Accordingly, the plaintiff is able to establish the prima facie case of the valid patent.

52. It appears to the Court that suit patent is a valid patent as the efficacy of invented compound, subject matter of suit patent, is admitted by the Defendant. Thus, the infringement is not seriously disputed by the Defendant.

53. The defendant in order to show prior art has merely filed certain documents without explaining as to how they invalidate the suit patent. There is no required pleadings and argument advanced by the defendant. Rather the statement was made at the bar by the learned senior counsel on behalf of the defendant that in case it is valid patent, the case of infringement is made out. Thus, from the entire facts and material placed on record, it is clear that prima facie, suit patent is a valid patent. No credible defence is made. The defendant has infringed the suit patent. Thus, the plaintiffs are able to make out a case for infringement of suit patent.

54. About the infringement, the defendant has not filed an expert affidavit has been filed by the defendant in order to show

that the impugned drug launched by the defendant does not infringe the suit patent of the plaintiff.

55. On the other hand, the Plaintiffs have also filed on record the analysis of Defendant's product by way of HPLC and Mass spectrometry in the affidavit of Alessandro Allodoli in support thereof. As per expert opinion, the inhalation powder in the Defendant's product contains INDACATEROL which confirms infringement.

56. It appears from the submissions of the defendant that its main argument is rests upon all the grounds available under Section 83 of the Act as well as on the issue of public interest. While reading of Section 83, the defendant has tried to interpret the said section along with the Section 48 of the Act and submits that the monopoly rights granted under Section 48 are subject to Section 83 of the Act and in case there is no compliance of various conditions of section 83, normally no prima facie is made out by the patentee. Section 83 has to be considered while considering the issue of injunction. If patent is not worked and is being misused only by the patentee in order to enjoy the monopoly on importation and the exercise of patents rights 'impedes promotion of public health and nutrition' and are abused and if the exercise of patent rights 'prohibits the Central Government from taking measures to protect public health'. If the product is not made available 'at reasonably affordable price' to the public then no prima facie case is made out.

57. There is line of authorities emerging from United States stating that public interest is fourth ground to refuse the injunction if the injunction to be granted in a given case is oppressive or extremely harsh to the society or the affected industry. This Court is of the view that on the sole ground of public interest is the one which can be said to be an offshoot of balance of convenience and the comparative damage as one has to see comparative inconvenience of the plaintiff vis-à-vis the defendant and the other affected parties. Therefore, the said ground of public interest is not the one which can be said to be present in the traditional rules governing the grant or non grant of injunction.

58. The Division Bench of this Court in the case of ***Telemecanique & Controls (I) Limited vs. Schneider Electric Industries SA,*** 2002 (24) PTC 632 (Del) (DB), decided by Davinder Gupta (Acting Chief Justice) and Sanjay Kishan Kaul, J., in paras 28, 30 and 31 held as under :

> "28. A further aspect which has to be analysed arose from the subsequent application filed by the appellant IA 6504/2000 alleging that the patents of the respondent had not been worked and since they were not being commercially exploited, no injunction could be granted in favor of the respondent. This plea is sought to be again forcefully contended before us by counsel for the appellant. The Division Bench judgment of this court in Franz Cavern Huemer v. New Yash Engineers 1996 PTC (16) 232 has been considered by the learned Single Judge. There can be no doubt about the proposition that since the patents create a monopoly, they must be

commercially exploited and the parties are not to only register a patent and sit tight over it. However, Mr. Rohatgi, learned senior counsel for the respondent sought to rely on the statement of working of patents filed in the year 1998-99 to contend that the patents are being exploited and thus the present case would not fall within the parameters laid down in Franz Xaver's case (supra) to categories the patents in the present case as one which are not commercially exploited and thus leading to a conclusion that public was being denied the benefit of such patents by its lack of user. The learned Single Judge accepting this contention concluded that he was not satisfied at this stage that the five patents are not being worked by the respondent in view of the statement produced by the respondent for the year 1998-99.

30. It has to be appreciated that undoubtedly patent creates a statutory monopoly protecting the patentee against any unlicensed user of the patented device. Thus once a violation is established in case of a registered patent, subject of course, to the patent being used, it will not be permissible to contend that the said patentee is not entitled to an injunction. A monopoly of the patent is the reward of the inventor. It is also to be appreciated that law of the patent is slightly different from the law of copyright and trademark as the patent is granted only for a period of 14 years. It is also relevant to note that in the agreement of technical services dated 28.11.94 there is no mandate for the appellant to provide technical information to the appellant in respect of the manufacture of any other items but the only requirement is that the same can be done if terms and conditions are agreed upon between the parties. If the respondent would have provided D2 range of products to the appellant it would have been entitled to royalty in terms of Clause 6.4 of the said agreement. It is thus difficult to believe, as stated

above, that there could be a license to copy and that is a major factor which has weighed with us in deciding the present appeal. It may also be added that Section 83 of the Patent Act, 1970 falls under Chapter XVI dealing with the working of patents, compulsory licenses, licenses of right and revocation. Section 83 by its wording refers to the exercise of powers conferred by the said Chapter and thus in view of their being exploitation of the patent in the country by sale of product by the respondent, the public is getting the product and is not deprived of its benefit.

31. We would also like to note that while making submissions in rejoinder Mr. Arun Kathpalia, learned counsel for the appellant, sought to make submissions that in view of Section 83 read with Section 90(d) of the Patents Act, 1970 the patent has to be worked out in India by manufacture and not by import. Mr. Kathpalia sought to rely on the commentary of Terrel on the Law of Patent, 13th edition chapter X para 10.07, 10.09, 10.10, 10.13, 10.14 and 10.17. Mr. Kathpalia submitted that same principles would apply in respect of the Indian law and thus in the absence of definition of commercial scale, natural and ordinary meaning should be given to the expression. He submitted that in terms of the said treaties the general principles set out are that a patentee must manufacture the product in that country and it should not also be mere improvements. We have, however, considered this aspect aforesaid and have come to the conclusion that there is no force in the submission of the appellant."

59. It is settled law that an interim injunction may be granted if the defendant has applied for a compulsory licence but he infringes the patent during a period when his application is still pending.

60. It is also settled law that an injunction may be granted in respect of a single claim even though other claims in the specification are not prima facie valid. The Defendant cannot be permitted to infringe the patent unless the approval of the Controller for seeking compulsory licence.

61. In the case of ***Paschim Banga Khet Mazdoor Samity Vs. State of W.B.*** (1996) 4 SCC 37 it was observed that in a welfare State it is the primary duty of the Government to secure the welfare of the people and providing adequate medical facilities for the people is an essential part of the obligations undertaken by the Government in a welfare State but in the context of the Government hospitals run by the State and the medical officers employed therein failing to perform their duty.

As far as reasonable price of the drug in question is concerned, there is National Pharmaceutical Pricing Authority, an organization of the Ministry of Chemicals & Fertilizers, Government of India established *inter alia* to fix / revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of medicines in the country under Drugs (Prices Control) Order issued from time to time. Attention in this regard is also drawn to the National List of Essential Medicines drawn up under the Prices Control Order.

62. The case of the Plaintiff is that COPD patients were being treated with the assistances of many drugs available in the market prior to 2010 before INDACTEROL was introduced.

63. The plea of Plaintiff is that importation is an acknowledged method of working; the facilities at Switzerland are geared to produce increased quantities and in fact, the Plaintiff through LUPIN Ltd. has commissioned a study in consultation with leading pulmonologists to arrive at more accurate figures of demand and if demand increases, the price would be inevitably revisited. The plaintiffs have filed an affidavit along with the Lupin in order to demolish the issue raised by the defendant on this aspect. The relevant extract of the said affidavit of Mr.Kuldeep K Wakhloo is reproduced hereunder:

> "4. I state that the Plaintiff No.2 has from time to time provide us with full, proper and timely supply of the Product based on our forecast and request mechanism. Besides, Lupin also ensures that it has adequate quantities of the Product i.e. at least 60 days of stock ready and available with it at all times for supply to patients situated across India.
>
> 5. Lupin is located across India through its 28 CNFs (carrying and forwarding agents) based in all the states and a central warehouse located in Mumbai through which it distributes the Product throughout India thus ensuring full coverage and optimal reach of the Product to every nook and corner of the country.
>
> 6. To further substantiate what is stated herein above, Annexure I hereto provides a list of stockists (wholesalers) who are being catered to by Lupin for supply of the Product. The list is indicative and not exhaustive to ensure brevity.

> 7. Lupin, on its part, continually ensures that there is enough and more stock of the Product available at all times with retail chemists through its elaborate network of stockiest and any request for the Product is promptly addressed. There is enough supply of the drug to Government hospitals from where Lupin received a demand and no unfulfilled demand has been received by Lupin so far.
>
> 8. In the circumstances, neither Lupin nor I have received any intimation of shortfall or short supply or non-availability of the Product across the territories that Lupin operates.
>
> 9. There has never been any unfulfilled demand received from any place in India. Lupin always has enough stock of Indacaterol to fulfil any demand and has never faced any short fall in supply of Indacaterol from Novartis since 2012."

64. It has come on record that the Plaintiff No.1 has sold INDACATEROL in India worth over Rs.3.2 crores in 2013. The affidavit filed by Kuldeep K. Wakhloo on behalf of Lupin Ltd., which states that there has never been any unfulfilled demand received from any place within India and Lupin always has sufficient stock to meet the demand in the Indian market. The Defendant has relied upon IMS data to show the sale of INDACATEROL in the market by Lupin to retailers. The deponent deposed that there is much more supply of INDACATEROL by way of import by Plaintiff No.2 in India than sold by Lupin. Lupin has also filed an affidavit dated 15.12.2014 which says that INDACATEROL is supplied all over

India by Lupin. Lupin has deposed that it has more INDACATEROL in stock than the demand and there has never been any shortfall of supply of INDACATEROL. Lupin has also deposed that it is supplying to Government Hospitals and Chemists all over India.

65. It is submitted by the plaintiffs that there are four categories of COPD conditions:

(a) Mild COPD condition;
(b) Moderate COPD condition;
(c) Severe COPD condition;
(d) Very severe COPD condition.

It is also the case of the plaintiffs that INDACATEROL as a monotherapy is only a treatment for "mild and moderate" categories of COPD patients and that apart there are other drugs (including those marketed by the Defendants) for "mild and moderate" COPD categories. In fact, the condition of the patient is often wrongly diagnosed for Asthma instead of COPD. Often mild or moderate condition of COPD is not detected by physicians in time and there are various factors responsible for lack of timely and accurate assessment of mild and moderate COPD conditions. There is no data available as to what is the percentage or number of mild and moderate COPD patients. The alleged figures suggested by Defendant are therefore incapable of establishing the allegation of short supply raised by it. This is particularly the case as the Defendant's calculation assumes that INDACATEROL is the only drug to treat COPD

and that INDACATEROL should meet all the demand for drugs to treat COPD.

66. There is a force in the submission of Mr.Subramanium that the plaintiffs are not expected to flood the market with INDACATEROL without reasonable demand. Medical practitioners have various options of drugs to choose from including that of the Defendant.

67. Before introduction of the INDACATEROL of the Plaintiffs, it is Defendant's drugs (among others) which were prescribed treatment for COPD patients. If the Defendant, despite being leading marketer of COPD drugs over last several decades, could not alter the number of COPD patients in need for treatment, the defendant cannot take the advantage of the Plaintiffs of not fulfilling the demand of COPD drug. As admitted by the defendant that COPD cannot be cured but only treated and therefore, the plaintiffs are correct in saying that the Defendant is merely relying on COPD data to raise the issue of public interest in order to infringe the suit patent.

68. It is submitted by the plaintiffs that All COPD patients are not INDACATEROL patients. There is no data available or provided by the Defendant that what is the number of INDACATEROL patients and how the said demand is not fulfilled by the Plaintiffs. There is no explanation as to why and how INDACATEROL is the only treatment for mild or moderate COPD patients. The technology to manufacture INDACATEROL has been made available by the Plaintiffs by disclosure in patent

specification as well as by submitting clinical data and the formulation details before the Drug Controller General of India. The case of the plaintiffs is that the Defendant has managed to replicate.

69. It is correct that the price of the Defendant's drug is not less as compared to drug of the Plaintiffs. Plaintiffs submit that the Defendant has neither invested in any research and development of invented compound nor invested in any clinical trials or market promotion of the drug. The price of patented and invented drug INDACATEROL is likely to be higher than that of the Defendant. The explanation given by the plaintiffs with regard to high price is that cost of innovation of one successful drug is USD 2.6 billion (Rs.1645 crores).

70. The plea of the defendant has no force as if setting up of a manufacturing unit is imposed as a condition precedent to patent protection, it would be contrary to the scheme of the Act as under various provisions for granting the compulsory licences, the said plea is available. The defendant in the present case has not moved any application for obtaining the compulsory licence knowingly that unless the approval is granted, the defendant would not be entitled to manufacture the drug and further there is a presumption of valid patent if an application for compulsory licence is filed before the Controller of Patents.

71. With regard to the argument of the Defendant that the Plaintiff is not manufacturing the drug in India is concerned, the

requirement of law is limited to working the patent in India so that the same is available to public at large. It is not essential that the patent must be worked by manufacturing the patented product in India. Reliance is placed on ***Telemecanique vs Schneider {2002 (24) PTC 632 (DEL) (DB) para- 31}***.

72. The arguments of the defendant have no force that the rights conferred under Section 48 are subject to Section 83. The argument of this nature would go against the scheme of the Act. The Act does not mandate that no patent protection would be granted to a patentee unless the local manufacture is undertaken.

73. It is not denied by the defendant that the defendant has applied and abandoned its applications in respect of several drug formulation involving INDACATEROL. The Defendant has not disclosed the same in its reply. The said facts were withheld from the Court. The Defendant has failed to disclose the details of rejected patents for compounds involving INDACTEROL. The justification given by the defendant on this aspect is for non-disclosure of fact is very strange.

74. The case law cited by the Defendant does not help the case of the defendant. All are cases in which the interim injunction was denied because the Plaintiff failed to establish a prima facie case of infringement or there was a credible challenge to the validity of the patent. Unless there is a credible challenge to the validity of the patent itself, the Courts will not include any alleged public interest as a factor to exercise

discretion. It was observed in the judgment of ***Roche Vs. Cipla 2009 (40) PTC 125***, cited by the Defendant, that the Plaintiff failed to establish prima facie case of infringement and on the contrary, defendant successfully raised credible challenge to the validity of the patent and the Courts have accepted the plea of the defendant in that case on the basis of defence raised. However, such circumstances are missing in the present case.

75. In case of *"**Franz Xaver**" (AIR 1977 Delhi 79)* and ***Sandeep Jaidika's*** *(2014 (59) PTC 234 (Del)*, interim injunction was denied since there was no working of the patent at all which is not the case here. In case of *"**Glaverbel**" (2010 (43) PTC 630 (Del)*, the court observed that the Form 27 did not disclose any commercial working of the patent. The present case is not a case where the patent drug is not available at all. Rather the case of the defendant is that there is a deficiency of the patented drug of the plaintiffs. The said plea is denied by the plaintiffs.

76. The judgment of "***BAYER Corporation***" of High Court of Bombay, was in context of compulsory license issue. The judgment of *"Jeevan Jyoti" 2008 ILR (1) 1088* was in a writ petition where the amendment of The Patent Act was challenged. The reliance of the Defendant on these judgments is erroneous.

In case once it is held by the Court that it is a valid patent and it has been infringed by the defendant, normally an injunction order can be passed. See:

(i) In the case of ***Bajaj Auto Vs. TVS Motor Company Ltd.***, *2008 (36) PTC 417 (Madras)* wherein it was held in paragraph 25 that in a case where a person creates what is in substance the equivalent of a patented article, the creation would be an infringement of the patented article and trifling and unessential variations would be ignored.

ii) In the case of ***Raj Prakash Vs. Mangat Ram Chowdhary***, *AIR 1978 Del 1* wherein it was held in paragraph 25 that minor variations in the two relevant products are irrelevant for the purpose of deciding whether there is infringement and if the infringing article is an equivalent of the patented article, infringement would be proved.

iii) In the case of ***Hind Mosaic and Cements Works & Anr. Vs. Shree Sahjanand Trading Corp.****, 2008 (37) PTC 128 (Guj) (DB)* wherein the Court relied upon the principles for grant of interim injunction and also held that the 'Expert's report' ought to have been considered by the Court.

iv) In the case of ***Wockhardt Ltd. Vs. Hetero Drugs Ltd. and Ors.,*** *2006 (32) PTC 65 (Madras)* wherein the Court held (in paragraph 17) that relief by way of interlocutory injunction is granted to mitigate the risk of injustice to the plaintiff during the period before certain uncertainties could be resolved and to avoid such injury

to the plaintiff that he cannot be adequately compensated for even if the uncertainty is eventually resolved in his favour at the trial.

77. It is argued by the plaintiffs that the alleged shortage of the patented drug of the Plaintiff cannot be the cause of increased COPD incidence as there are several drugs on the Indian market for treatment of COPD for many years. Drugs for treatment of COPD, including INDACATEROL, are "maintenance therapy" so as to treat different grades of COPD condition. The reliance of an alleged COPD epidemic even otherwise does not allow or give any justification to infringe the suit patent.

78. The Plaintiff came to know about the Defendant's launch of INDACATEROL on 30th October, 2014 through newspaper report in a newspaper "The Economic Times". On 7th November, 2014, the Plaintiff instituted trade mark infringement suit wherein the Defendant undertook to change its trade mark UNIBREZ being deceptively similar to registered trade mark ONBREZ of the Plaintiffs. The Defendant's conduct would show that the defendant was not merely trying to use the Plaintiffs' patented drug but has also infringed the trade mark of the plaintiff. Ultimately on the basis of undertaking the said suit was decreed in favour of the plaintiff and against the defendant by Order dated 17th November, 2014, the suit for trade mark infringement being suit no. 3356/2014. The Plaintiffs in the said

action allowed the Defendant to dispose of their stock which was disclosed to be 23837 strips. The defendant has also filed the affidavit dated 21st November, 2014.

79. With regard to objection of the defendant about Order II Rule 2 CPC, the same is without any force. The suit No.3356/2014 was in respect of cause of action arising from infringement of plaintiff's trade mark ONBREZ on account of use of deceptively similar trade mark UNIBREZ used by the defendant. The cause of action of the present suit is on account of infringement of suit patent IN 222346 on account of manufacture and sale of patented drug namely INDACATEROL including INDACATEROL Maleate by the defendant. Both are separate and distinct causes of action. The said suit was only pertaining to infringement of trade mark. The question of application of provision of Order II Rule 2 CPC does not arise. Even otherwise, while passing the consent decree against the defendant, the said position was clarified by the plaintiff who reserved its right to file a separate suit for infringement of patent.

80. The plaintiffs in their rejoinder have analyzed the articles and the data produced by the Defendant. They submit that the articles would show about the problems in diagnosis, management and follow up of COPD patients. (Article titled Chronic Obstructive Pulmonary Disease Indian guidelines) and lack of awareness of the disease, its symptoms or implications preventing persons at risk from seeking help from their primary

care positions. The plaintiffs case is that spirometries are not routine and diagnosis is generally symptom based. The prescription of inhalation devices is attributed to the "terminal stage" and the device carry a virtual stigma in rural strips and most of patients would go for treatment to local Hakims practicing local medicines and faith healers. The following is the reply of the plaintiffs to the publications and articles referred by the Defendant do not suggest that there is unavailability or shortage of COPD drugs.

a. Article titled "A review of Population Studies……." By S. K. Jindal: The article acknowledges that COPD is one disease which is preventable to large extent if tobacco smoking is controlled;

b. Article titled Indian Study on Epidemiology of Asthma ……" The article recognizes that there are obvious limitations of symptom based diagnosis and large practitioners practicing in small places do not differentiate between Asthma and COPD and inhalers and bronchodilators sometimes are used for non-symptom of cough. Tobacco, ETS exposure and indoor explorations are responsible for COPD condition.

c. Article titled "COPD an Unrecognized Epidemic in India"; This article recognizes that COPD is a global phenomenon prevalent in various countries and it is not something which is unique to India. According to this article the prevalent rates of COPD in Western countries had been higher than Asian countries.

81. The Defendant has apparently raised the defences which are in the nature of pleas and grounds permitted to be raised for

seeking compulsory license under Chapter XVI of The Patents Act, 1970 under Section 84 of The Patents Act, 1970. Any party who intends to obtain compulsory license under these provisions obviously has to acknowledge the validity of patent and the Controller of the patent under the scheme of the above mentioned provision has to consider the application who may or may not grant the compulsory licence because of existence of valid patent.

82. It has neither approached the Plaintiff for seeking any voluntary license nor has it approached the Controller for seeking compulsory license. The defendant rather made a petition under Section 66 and 93 of the Act before DIPP and commenced the infringing activity even without awaiting any decision on such petition. Defendant while accepting the usefulness and working of patent of INDACATEROL decided to manufacture INDACATEROL and at the same time to infringe the Plaintiff's patent of INDACATEROL has approached the DIPP.

83. Let me now evaluate the case of the parties on the parameters of the grant of temporary injunction which are prima facie case, balance of convenience and irreparable harm. The plaintiff has established the prima facie case of the valid patent in as much as that on the date of hearing of the suit, the plaintiffs patent was neither challenged in the pre grant opposition or post grant opposition except the grounds on invalidity which have been raised by the defendants in the

present suit. As regards the grounds of invalidity, the defendants have merely urged these grounds by placing reliance upon the documents which according to the defendants constitute prior arts without explaining to the court and to the other side as to how these documents can be categorized as prior arts. The plaintiff on the other hand provides the points of the distinction towards the earlier patents relied as prior arts vis a vis the present patent. Furthermore, there exists a contra material on record which suggests that the defendant maintains the position that there exists high level of efficacy which is mentioned in the application filed by the defendant under section 66 and 92(3) of the Patents Act seeking a revocation on the premise of the public interest.

84. The balance of convenience and irreparable harm shall not be caused to the defendant in as much as the defendant has recently launched the product in the market in October 2014 and the plaintiffs have immediately filed the suit before the court. Thus, the defendant as a private party is less inconvenienced in case the interim order is passed against the same as against the plaintiff who would be put to prejudice as the patent comprises of novel and valuable invention which has been well known product of the plaintiff not merely in India but across the globe which is evident from the documents filed on record including the sale figures, existence in the other countries and high efficient nature of the product. **Thus, irreparable harm and inconvenienced is caused to the**

plaintiff if the defendant is allowed to manufacture the products under patent without any interim arrangement as it will encourage the generic companies to make the medicines of the invented products and making the invention public without appropriate reward to the inventor.

85. The inconvenience is also not caused to the defendant at this stage as the defendant is raising the grounds available under section 83 and 84 of the Act which are necessary for exercising the powers under the chapter XVI of the Patents Act by the controller and the Central government. This court cannot adjudicate those grounds on premature basis without the defendant approaching the right forum solely on the basis of public health sentiment without the defendant approaching the appropriate forum and urging the grounds therein.

86. Thus, the defendant can always seek the compulsory license before the appropriate forum under the provisions of section 83 and 84 of the Act if it is advised to by urging the grounds urged before this court for non working of the patent or inability of the plaintiff to comply with demands or monopoly by way of importation etc. Accordingly, the defendant can pursue its remedies if the defendant has good case on the grounds of the compulsory license and in which case the appropriate forum may allow the defendant to manufacture the patented products if the case of the defendant is found to be plausible by the appropriate forum and the defendant can always approach this

court for modification of the interim order in case the compulsory licensing tribunal comes to the said conclusion.

87. In case the entire scheme of the Act is examined carefully, it appears that if the patent is valid, the defendant has failed to establish prima facie credible defence and the case of infringement is made out by the patentee, the patentee may be entitled for injunction.

88. Therefore to say that public interest is a complete exception to the patent would not be correct as otherwise the rights granted by the sovereign towards monopoly would be undermined by too broadly interpreting the public interest. The ground of public interest can be invoked once the court finds that damages is adequate relief which has been held in the line of authorities emerging from US where the courts have imposed heavy sums upon the defendants towards permitting the usage of patents.

89. The reliance of the Defendant on Article 21 is misplaced in as much as the legislature, in furtherance of Article 21 has provided protection under Sections 48 of the Patents Act. Article 21 cannot be pressed into service by an infringer seeking to justify the infringement of a valid patent and the statutory rights conferred by the statute. The Statute, it is nowhere alleged by the Defendant violates Article 21. There is a supply of INDACATEROL by the Plaintiffs to fulfill the present demand of its drug.

90. With regard to ***EBAY INC. V. MERCEXCHANGE LLC*** *[547 US (2006)]* judgment is concerned, the US Supreme Court has reiterated the traditional principle of equity which should also be applied to patent disputes and remanded the matter to District Court for reconsideration which had denied the injunction without applying such principle. The Supreme Court held that neither the District Court nor Court of appeal based their decision on these principles. The District Court denied injunction on the ground that the Plaintiff had failed to establish any commercial activity of the patented invention. This judgment does not help the case of the defendant and has no application to a case such as the present one where there is prima facie evidence of commercial working of suit patent.

91. The Defendant is yet to launch the product under the new brand name. The defendant has also applied for several patent applications containing INDACATEROL and abandoned the said fact in its reply. The defendant has filed representation before DIPP and without awaiting the adjudication launched the infringing product in the market after two days. The defendant if so very much concerned about the welfare of public and patents and its grounds are genuine and correct, it could have filed the application for grant of Compulsory Licence.

92. Lastly, this Court has to deal with an important issue of public interest. The Defendant, inter alia has taken the defence of public interest, non-availability of Plaintiffs' drug and its price. In support thereof, the Defendant has referred few articles which

refer to Chronic Obstructive Pulmonary Disease (COPD) as a disease which has allegedly reached an epidemic proportion and as there are 1.5 crores COPD patients in India which needs to be treated and the plaintiffs have failed to fulfil their duties, the patients are getting the drug and who are getting, they receive on higher price.

93. The argument on behalf of the defendant side is that under Article 21 of the Constitution of India to say that the citizens of India are entitled to access to medicines at reasonable cost and in reasonable quantity.

94. It is stressed by the defendant that issuance of interim injunction will amount to denial of fundamental right under Article 21 to the citizens.

95. There exists a dispute between the parties as to whether the grounds available for the compulsory licensing more specifically the requirements of public interest and the reasonable requirement of the public with respect of the patented invention not being satisfied and the general principles applicable to working of the patented invention are available or not in order to resist the grant and non grant of the injunction.

The Scheme of the Compulsory Licences

96. In the Patent Law by P. Narayanan, the Scheme of the Compulsory Licences is discussed. Relevant contents are mentioned below:

A compulsory licence to work a patented invention may be granted by the Controller to an interested person on one of the following grounds:

(i) that the reasonable requirements of the public with respect to the patented invention have not been satisfied; or

(ii) that the patented invention is not available to the public at a reasonable price.

The Controller can entertain an application for compulsory licence only after the expiration of three years from the date of sealing of the patent. Failure to satisfy the reasonable requirements of the public may arise from any one of the following causes, namely --

(a) Inadequate manufacture in India or failure to grant licences on reasonable terms resulting in (1) prejudice to an existing trade or industry or its development, (2) prejudice to the establishment of a new trade or industry in India, (3) prejudice to the trade or industry of any person or class of persons, (4) demand for the patented article not being met adequately by local manufacture, (5) failure to develop an export market for the patented articles made in India, (6) prejudice to the establishment of commercial activities in India;

(b) Prejudice to the establishment or development of trade or industry in India in goods not protected by the patent arising from restrictive conditions imposed by the patentee;

(c) Non-working of the patent in India on a commercial scale;

(d) Demand for the patented article being met by importation from abroad; and

(e) Commercial working of the patented invention in India being hindered or prevented by import of the patented articles from abroad.

As a result of the failure of the patentee to manufacture the patented article or its essential parts in India to an adequate extent and supply them on reasonable terms; or as a result of the refusal of the patentee to grant licences on reasonable terms:

(2) an existing trade or industry or its development is prejudiced; or
(3) the establishment of any new trade or industry in India as prejudiced;
(4) the trade or industry of any person or classes of persons trading or manufacturing in India is prejudiced;
(5) the demand for the patented article is not being met to an adequate extent or on reasonable terms from manufacture in India; or
(6) a market for the export of the patented article manufactured in India is not being supplied or developed; or
(7) the establishment or development of commercial activities in India is prejudiced.

By reason of the conditions imposed by the patentee upon the grant of licences, or, upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India is prejudiced. The patented invention is not being worked in India on a commercial scale to an

adequate extent, or to the fullest extent that is reasonably practicable. The demand for the patented article in India is being met to a substantial extent by import from abroad either by the patentee or by persons claiming under him or by infringers.

In determining whether any one of the circumstances detailed in section 90 exists, the Controller has to consider the scope and meaning of expressions like manufacture in India to an adequate extent, supply on reasonable terms, licences on reasonable terms, trade or industry in India, trade or industry of any person or classes of persons, establishment of a new trade or industry in India, establishment or development of commercial activities in India, prejudiced, working on a commercial scale, worked to the fullest extent that is reasonably practicable and demand for the patented article.

The expression appears in Section 90(a). The phrase “adequate extent” is very elastic. To what extent the manufacture of the patented article is adequate will obviously depend upon the particular circumstances of each case. If the manufacture is to be considered inadequate such inadequacy must necessarily lead to one of the consequences mentioned in sub-clauses (i) to (iv) of clause (a). Thus it must result in causing prejudice to an existing trade or industry or its development, or the establishment of any new trade or industry, or the establishment or development of commercial activities in India. Alternatively, it must result in not meeting the demand for the patented article adequately from manufacture in India, or in the failure to supply or develop an export market for the goods. Adequacy of manufacture must

therefore be judged in the context of the extent to which it has satisfied the reasonable requirements of the public as defined and elaborated in Section 90 (a).

Section 84(1) provides that the patentee must make the patented invention available to the public at a reasonable price. Failure to do so will be a ground for granting compulsory licences. What is a reasonable price for the patented article will depend upon the circumstances of each case. It must be considered whether or not the price charged by the patentee is broadly speaking a bona fide one and is not a price adopted for the very purpose of checking and diminishing the demand for the home-manufactured article. If the price charged by a patentee for the home-made machine is higher than that supplied from abroad, a prima facie case for suspicion would arise.

The expression working on a commercial scale or its grammatical variation appears in clauses (c) and (e) of Section 90, Section 83(a) and Section 91(2). It is not defined in the Act. In ordinary parlance the phrase is used in contradistinction to research work, or work in the laboratory. Any working of the patent for the production of the patented article or the use of the patented process in the production of any articles for sale to the public would appear to amount to working on a commercial scale. The elastic phrase adequate extent appears in clauses (a), (a)(ii) and (c) of Section 90. Its precise meaning will depend upon the particular circumstances of the case and the context in which it is used. Thus in clause (a) the answer to the question whether the patentee has manufactured the patented article in India to an adequate extent will depend upon the extent to which such

manufacture or lack of manufacture was responsible for creating the situations detailed in sub-clauses (i) to (iv). Adequate is a word imputing equality or sufficiency in a proportion sense. In ordinary circumstances where there is no difficulty in the way of working an invention in India, and there are no other circumstances to be considered, adequate used in the context of sub-clause (ii) would appear to suggest a reasonably close relationship to the demand for the particular article India.

In clause (c) of Section 90 there is a reference to the patent not being worked to the fullest extent that is reasonably practicable. It is used as an alternative to working of the patent on a commercial scale to an adequate extent. The fullest extent to which an invention may be worked may mean the maximum rate of production which is practicable and necessary to meet the demand for the patented article. Section 90(c) is only one of the cases where if the circumstances mentioned therein are shown to exist, the reasonable requirements of the public with respect to the patented invention will be deemed not to have been satisfied. The expression “fullest extent that is reasonably practicable” should therefore be construed with reference to the public demand for the patented invention. The same expression appears in Section 83(a).

The words “demand for the patented article” appear in clauses (a)(ii) and (d) of Section 90. In clause (a)(ii) the scope of the phrase is not restricted to the demand in India and would, therefore, appear to include demand for the article for export purposes. Clause (d) refers only to demand for the patented article in India. The use

of the words “is being met” in clause (d) would suggest that the demand for the article for the patented article referred to in the clause must be an existing one in India and not one which might be created by exploiting the invention. However, clause (a)(ii) would appear to cover existing demand for the patented article not only in India but anywhere in the world. What would be the position where there is no demand for the patented article in India for the patented invention? Section 83(a) would appear to suggest that it is, for patents are granted not only to encourage inventions but also to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable. While dealing with the abuse of patent monopoly under Section 27 of the U.K. Act of 1907 it was observed that it is not correct to say that the patentee has no obligation to show any substantial manufacture here until a demand for the patented article or process had arisen or been created. The consideration of the adequacy of manufacture in this country does, no doubt, depend to some extent upon the demand existing, there is no obligation on a patentee to start an industry here. If he does in fact manufacture in foreign countries, and if there is in fact a demand for the article or process abroad, the absence of any demand here does not seem to be a valid excuse. The patentee must, in such cases, make an effort to create a demand here, and the establishment of an industry will in itself help to create in many cases a demand for the article or process in question.

In deciding whether or not to grant a compulsory licence under Section 84 (5) the Controller should take into account the following matters:

(1) the nature of the invention;
(2) the time which has elapsed since the sealing of the patent;
(3) the measures already taken by the patentee or any licensee to make full use of the invention;
(4) the ability of the applicant to work the invention to the public advantage.

In granting a licence the Controller will always take into consideration the public interest. Compulsory licences are in fact granted to satisfy the reasonable requirements of the public. The Controller is required to take into account the ability of the applicant to work the invention to the public advantage. The provisions for compulsory licences are designed to prevent the failure of the patentee to satisfy the reasonable requirements of the public as distinct from those of particular individuals. It is this failure which is in terms made the ground for granting a compulsory licence. Section 90 merely specifies particular circumstances, in which, if proved to exist, the reasonable requirements of the public will be deemed not to have been satisfied. Mere default to supply the patented article or refusal to grant a licence to a particular individual would not necessarily amount to default to supply the patented article or refusal to grant licences within the meaning of Section 90. There may well be an adequate supply of the patented article to satisfy the requirements of the public, or the patentee may have granted an adequate number of licences on reasonable terms to satisfy the same requirements, and in that case his refusal to supply or grant a licence to a particular person may not be a default within the meaning of Section 84. In order, therefore, to establish a case for compulsory licence, the applicant may have to prove not only default towards himself, but default towards the

public generally, or that part of it which is interested in the matter in question. Section 84 is really for the benefit and protection of the public and is not, primarily at any rate, intended to confer benefits on individuals. The Controller or the Court will therefore, look primarily not to the interest of the individual, but to the interest of the public.

In an application for compulsory licence under Section 84 the Controller should exercise his powers with a view to secure:

(a) that patented inventions are worked on a commercial scale in India without undue delay and to the fullest extent that is reasonably practicable; and
(b) that the interests of any person for the time being working or developing an invention in India under the protection of a patent are not unfairly prejudiced.

The application of these two clauses may sometimes lead to conflicting interests to be reconciled. Thus, where a patented article is being worked and developed by one person, another person may come forward for a compulsory licence to work a patent relating to better or cheaper article of the same kind for the same purpose. The latter patent, if worked on a commercial scale to the fullest extent, may make the articles made under the former patent obsolete, and may unfairly prejudice the interests of the person working that patent.

97. It is necessary to refer certain provisions of The Patent Act, 1970 as amended by The Patents (Amendment) Act, 2005.

The relevant Sections 48, 64, 83, 84, 107 and 108 of the same read as under:

> **"48. <u>Rights of Patentees</u>**
> **Subject to the other provisions contained in this Act** and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee–
>
> (a) where the subject matter of the patent is a product**, the exclusive right** to prevent third parties, who do not have his consent, from **the act of making, using, offering for sale, selling or importing** for those purposes that product in India:
>
> (b) where the subject matter of the patent is a process the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India:
> Provided that the product obtained is not a product in respect of which no patent shall be granted under this Act." **(Emphasis Added)**
>
> 64. **<u>Revocation of patents.</u>** - (1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, [5][be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court] on any of the following grounds that is to say-
>
> (a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date

contained in the complete specification of another patent granted in India;

(b) that the patent was granted on the application of a person not entitled under the provisions of this Act to apply therefor: [1] [***]

(c) that the patent was obtained wrongfully in contravention of the rights of the petitioner or any person under or through whom he claims;

(d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;

(e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in section 13: [1] [***]

(f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim: [1] [***]

(g) that the invention, so far as claimed in any claim of the complete specification, is not useful;

(h) that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed,

that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection;

(i) that the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is not fairly based on the matter disclosed in the specification;

(j) that the patent was obtained on a false suggestion or representation;

(k) that the subject of any claim of the complete specification is not patentable under this Act;

(l) that the invention so far as claimed in any claim of the complete specification was secretly used in India, otherwise than as mentioned in sub-section (3), before the priority date of the claim;

(m) that the applicant for the patent has failed to disclose to the Controller the information required by section 8 or has furnished information which in any material particular was false to his knowledge;

(n) that the applicant contravened any direction for secrecy passed under section 35 [1][***] [2][or

made or caused to be made an application for the grant of a patent outside India in contravention of section 39];

(o) that leave to amend the complete specification under section 57 or section 58 was obtained by fraud.

[2][(p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

(q) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere]

(2) For the purposes of clauses (e) and (f) of sub-section (1)-

(a) no account shall be taken of [153] [personal document or secret trial or secret use]; and

(b) where the patent is for a process or for a product as made by a process described or claimed, the importation into India of the product made abroad by that process shall constitute knowledge or use in India of the invention on the date of the importation, except where such importation has been for the purpose of reasonable trial or experiment only.

(3) For the purpose of clause (l) of sub-section (1) no account shall be taken of any use of the invention-

(a) for the purpose of reasonable trial or experiment only; or

(b) by the Government or by any person authorised by the Government or by a Government undertaking, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention directly or indirectly to the Government or person authorised as aforesaid or to the Government undertaking; or

(c) by any other person, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention, and without the consent or acquiescence of the applicant or of any person from whom he derives title.

(4) Without prejudice to the provisions contained in sub-section (1) a patent may be revoked by the High Court on the petition of the Central Government, if the High Court is satisfied that the patentee has without reasonable cause failed to comply with the request of the Central Government to make, use or exercise the patented invention for the purposes of Government within the meaning of section 99 upon reasonable terms.

(5) A notice of any petition for revocation of a patent under this section shall be served on all persons appearing from the register to be proprietors of that patent or to have shares or interests therein and it shall not be necessary to serve a notice on any other person."

"**83.<u>General principles applicable to working of patented inventions</u>**

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

(a) that **patents are granted to encourage inventions** and to secure that the inventions are **worked in India on a commercial scale** and to the fullest extent that is reasonably practicable without undue delay;

(b) that they are **not granted merely to enable patentees to enjoy a monopoly for the importation** of the patented article;

(c) that the protection and enforcement of patent rights **contribute to the promotion of technological innovation and to the transfer and dissemination of technology**, to the mutual advantage of producers and users of technological knowledge and **in a manner conducive to social and economic welfare**, and to a balance of rights and obligations;

(d) that **patents granted do not impede protection of public health** and nutrition and **should act as instrument to promote public interest especially in sectors of vital importance** for socio-economic and technological development of India;

(e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;

(f) that the **patent right is not abused by the patentee** or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the **patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology**; and

(g) that patents are granted to **make the benefit of the patented invention available at reasonably affordable prices to the public**." (Emphasis Added)

84. <u>Compulsory licences.</u> -

(1) At any time after the expiration of three years from the date of the [170] [grant] of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:-

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.

(2) An application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be estopped from alleging that the reasonable requirements of the public with respect to the

patented invention are not satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.

(3) Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.

(4) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence upon such terms as he may deem fit.

(5) Where the Controller directs the patentee to grant a licence he may as incidental thereto exercise the powers set out in section 88.

(6) In considering the application field under this section, the Controller shall take into account,-

(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

(ii) the ability of the applicant to work the invention to the public advantage;

(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit :

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.

[Explanation .- For the purposes of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months.]

(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied -

(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, -

(i) an existing trade or industry or the development thereof or the establishment of any new trade or

industry in India or the trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) a market for the patented article manufactured in India is not being supplied or developed; or

(iv) the establishment or development of commercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or establishment or development f any trade or industry in India, is prejudiced; or

(c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing; or

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or

(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by -

(i) the patentee or persons claiming under him; or

(ii) persons directly or indirectly purchasing from him; or

(iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement.

107. **Defences, etc ., in suits for infringement.** –

(1) In any suit for infringement of a patent every ground on which it may be revoked under section 64 shall be available as a ground for defence.

(2) In any suit for infringement of a patent by the making, using or importation of any machine, apparatus of other article or by the using of any process or by the importation, use or distribution or any medicine or drug, it shall be a ground for defence that such making, using, importation or distribution is in accordance with any one or more of the conditions specified in section 47.

108.**Reliefs in suit for infringement.**— (1) The reliefs which a court may grant in any suit for infringement include an injunction (subject to such terms, if any, as the court thinks fit) and, at the option of the plaintiff, either damages or an account of profits.

(2) The court may also order that the goods which are found to be infringing and materials and implements, the predominant use of which is in the creation of infringing goods shall be seized,

forfeited or destroyed, as the court deems fit under the circumstances of the case without payment of any compensation."

98. From the collective reading of the aforementioned provisions and the entire scheme of the Act, the following position can be discerned:

a) From the plain reading of the opening words of the Section 83 of the Act which reads, "without prejudice to other provisions contained in this Act, in exercising of the powers conferred by this chapter", it is clear that the general principles stated in the said chapter are operative for the purposes of the exercise of the powers under the Chapter XVI which is chapter XVI dealing with the working of the patents, compulsory licensing and revocation thereof on the ground of the non working. Thus, the general principles relating to the working of the patent as stated in section 83 are required to be considered by the controller/ authority or central government for the purposes of exercising the powers under this distinct chapter XVI.

b) The reading of section 48 of the Act provides for the right of the patentees which is "subject to other provisions contained in this Act and conditions specified in section 47". The collective reading of section 48 read with section 83 of the Act would reveal though the rights of the patentee are subject to the

other provisions contained in the Act and conditions specified in section 47 and offcourse the same shall be subject to the provisions of chapter XVI as well but the power to be exercised under chapter XVI in the form of the several remedies available to the person interested compulsory licensing application, revocation on the grounds of the non working of the patent etc are all required to be adjudicated and considered on the basis of the grounds and consideration provided under the provisions of section 83, 84 and 85 of the Act. That is why section 83 provides “without prejudice to other provisions contained in this Act” which means that the mechanism prescribed under chapter XVI and the considerations for exercising of the said powers are independent and distinctly provided under the said head. The combined effect of language used in section 48 and section 83 is that though the rights granted to the patentee are subject to the other provisions contained in the Act which would include the provisions of section 83 to section 90 which would have bearing upon the exercise of said rights of the patentee. But the exercise of the powers and the considerations operating for such exercise of the powers by the controller/ central government are prescribed under section 83 of the Act distinctly. The domain of the controller/ central government/ authority which is seisin

of the compulsory licensing application or revocation on the ground of the non working and considerations operating for deciding the said application are entirely distinct and independent as provided under the relevant provision including section 83.

c) Accordingly, It does not follow that merely because section 48 rights are subject to other provisions of the Act and section 83 provides general principles which are applicable to working of the patented inventions which are applicable to exercise of the powers under chapter XVI would equally be applicable to the proceedings for infringement of the patent and/ or the counter claim challenging the validity of the patent which are governed by the distinct provisions under section 104 and section 107 of the Patents Act. This is due to the reason that the domains of the Civil Court, Controller, Central Government and other functionaries are prescribed under the Act which delimits their bounds and the matters which fall for their consideration. Thus, there cannot be real mix up between the domain of the civil court while hearing the suit for infringement of the patent and the tribunal/ controller hearing the compulsory licensing the application or revocation on the ground of the non working. As it is enacted under the provisions of section 83, the grounds which are relevant for the

purposes of the grant of the compulsory licensing can be urged and adjudicated before the competent authority and not by the civil court seized of the infringement proceedings.

99. In view of the aforementioned discussion, It is clear that the grounds which are available for the person interested while seeking an application for the compulsory licensing or revocation of the patent on the ground of non working of the patent could be urged before the relevant authority which will consider the matter and cannot be imported as a matter of defence to the suit for infringement as the civil court hearing the suit for infringement cannot transgress within the domain of the authority/ controller/ central government which are distinct functionaries having their powers and considerations specifically defined under the specific provisions of the Act. Even under the World Trade Organisation Trip Agreement, Compulsory Licences are receognized in order to overcome barriers in accessing affordable medicines and on other ground of non-workable of suit patent as per conditions prescribed under Sections 83 and 84 of the Act.

100. Consequently, the pleas which are specifically raised by the defendant that the plaintiffs are attempting to enjoy a monopoly for the importation of the patented article, patents granted do not impede protection of the public health and nutrition and should act as an instrument to promote public

interest, patents are granted to make the benefit of the patented invention available at reasonably affordable prices are all the considerations operating at the time of the exercise of the powers under chapter XVI which are for compulsory licensing, revocation on the ground of non working etc and are not available to the defendant while resisting the suit for infringement of the patent. Therefore, this court while hearing the application seeking the grant of the interim injunction may not refuse the injunction by forming any opinion solely on the ground as to whether the patented invention is sufficiently worked upon in India or whether the same is available to the public in reasonably affordable prices and the other pleas which overlap the grounds and considerations available in chapter XVI of the Act.

101. Having said this after analyzing the scheme of the Act, one cannot also be oblivious to the legal position which is that the grant and non grant of the injunction in the cases premised on the infringement of statutory rights including patents and trade mark rights are always the matter of the discretion which vests with the court and the said discretion has to be exercised judicially by the civil court on the basis of the sound judicial principles which include evaluation of prima facie case, balance of the convenience and irreparable loss as per the well settled principles of law laid by the apex court and by this court from time to time starting from the case decided by the Lord Diplock in the case of ***American Cynamide Co. v. Ethicon Ltd.***, (1975)

RPC 513, the equitable considerations which include justice, fair play are factors equally guide the court while adjudicating the grant and non grant of the injunction in the cases involving the statutory rights including patents and trade marks.

102. No doubt, it is true that the grounds for the grant of the compulsory licensing , revocation of the patent on the grounds of the non working which are distinctly provided under chapter XVI are not available to the defendant to be urged before the civil court hearing the suit for infringement of the patent. However, that does not by itself would mean that the court is precluded from weighing the case of the parties on the touchstone of the well established principles of law governing the field of the patent. The said well-established principles include weighing the case of the plaintiffs on the threshold of the larger public interest which is facet of the balance of the convenience. In the private lis between the parties involving the civil dispute, the grant of temporary injunction normally involves evaluating the balance of convenience of the parties by weighing which of the parties shall be more inconvenienced against the party which is less inconvenienced. There is another facet attached to the balance of convenience which is public interest.

103. In the field of intellectual property rights like trade marks and patents, public interest is one of the element which equally guide the court towards the grant and non grant of the injunction. In trade mark cases, where there exists a likelihood

of the confusion and deception in an action for deceit which is passing off, the public interest lies in favour of the plaintiff and in such a case, it is not merely the plaintiff who is inconvenienced if the injunction is not granted but the larger public interests in the form of consumer deception which is affected or inconvenienced with the defendant's continuance of the tortious acts of the deceit and therefore, it is well recognized and said that the in the cases involving user of the identical and deceptively similar trade marks, normally the injunction in the form of interlocutory relief must follow.

104. **The public interest doctrine guide the cases of the patents as well especially in the cases wherein the innovations involve the life saving drugs or pharmaceutical preparations which would have bearing upon the life of the general public in the disputes involving the making of the life saving drugs affecting the lives of the larger segment of the public. The reason is very simple and plain which is that the manmade inventions cannot be said to be taking precedence over the life of the mankind. Therefore, some mechanism is devised by the courts so that the rights of the patentee is respected and simultaneously the public interests is equally not affected by balancing out the two militating interests. Thus, the balanced approach is adopted by the courts by imposition of the terms in the form of royalty to be paid by the third party to the patentee than to absolutely prevent the making of the patented**

product in the form of injunction where the disputed question of facts arise as to whether the invention is adequately worked in the country or not or where there exists a link between the patented product and the far reaching effect of the medicines upon the public health and well being of the public of the country in a case of such nature is made by the defendant.

105. The public interests doctrine has been invoked by the US courts number of times in the cases involving the patent infringement including but not limited to pharmaceutical disputes involving the life saving drugs. One of the cases which was decided by the US Supreme Court is the case of ***eBay Inc. v. MercExchange, L.L.C.***, 547 U.S. 388, 389 (2006) which is relating to business method patents as against the medicinal patents wherein the Majority opinion written by Justice Thomas, was rather short and solely dealt with determining the appropriateness of the Federal Circuit's general rule regarding permanent injunctions. The Court abrogated the general rule and mandated that, "[a]ccording to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief." The Court established that a plaintiff must demonstrate:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff

and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

The US Court remanded the matter before the district court for reconsideration and whereafter the District Court again after hearing the matter came to the conclusion that the public interests favour against the grant of the injunction. This element of the 4th factor of public interests evolved by the US Court which in my opinion was always present on weighing the case of the parties on the balance of convenience became the point of larger debate in US and across the globe in relation to decision in patent matters of diverse nature. Though the facts of the case in Ebay were distinct relating to business method patent and the negotiation of the patentee with others to license the said patent but not to Defendant in the said case, still the said principle has been widely accepted by US Court even in the cases involving the disputes over the patents in the life saving drugs.

106. The general trend after the decision of E Bay [supra] in the cases of Patent infringement of life saving drugs and therapies, clearly applies the principle of public interest and the four-factor test enunciated in the said case.

107. In the case of ***Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc*. 670 F. 3D 1171 (2012**) concerning involvement of Patent relating to prosthetic vascular graft which

was owned by Bard Peripheral and the infringement was done by the W.L. Gore which was the direct competitor of the Plaintiff under public interest factor, the Court analyzed the argument of both the parties and tried to predict the public health ramifications of granting the permanent injunction. In the words of the Court, it was observed thus:-

> ***"Given the utility of Gore's infringing products…… the important role of these products play in aiding vascular surgeons, perform life saving medical treatments, sound public policy does not favour removing Gore's items from the market. The risk is too grave. Placing Gore's infringing products out of the reach of Surgeons who rely on them would only work to deny many sick patients a full range of clinically effective and potentially life saving treatment, the Court finds that the strength of this fact along precludes it from imposing a permanent injunction [emphasis supplied]."***
>
> The matter went on appeal before Federal Court which affirmed the decision of District Court's denial of permanent injunction by holding that the award of an ongoing royalty instead of permanent injunction to compensate for future infringement is appropriate in some cases [emphasis supplied].

108. From the reading of EBay [supra], it is clear that even if EBay decision was not relating to the Patent involving life saving drugs, but was concerning with business methods Patents, still the Courts consistently followed the approach by

evaluating the case of the parties and adjudging the entitlement for the injunction from the standpoint of public interest even in the cases involving life saving drugs where the Courts have adopted the approach by looking at the prevalent position in the area specific and other attendant circumstances including the requirement of patients and physicians which affects on the public health. Thus, whether the public interest exists or nor in a case involving infringement of Patents is essentially a question of fact which has to be determined on case-to-case basis and no straight jacket formula can be devised in order to infer the public interest in a Patent infringement action. Suffice it to say that not merely the Courts in India but even the Courts in USA also believe that the element of public interest is attached in the cases involving Patent infringement in life saving drugs.

109. The Delhi High Court has approved the decision of E Bay [supra] while discerning the public interest at the time of deciding the interim injunction application in the case of ***F. Hoffmann-La Roche Ltd, ... vs Cipla Ltd. 148 (2008) DLT 598***.

110. From the reading of the aforementioned illuminating observations of Division Bench of Delhi High Court in the case of ***Hoffmann-La Roche*** *[supra]* at the interim stage which remained undisturbed till date and even in the final judgment, the conclusion was the same though on different grounds, it is beyond cavil of any doubt that the Indian Courts have also approved the same sentiments that are emerging from US

Courts that the public interest has vital role to play in the cases involving infringement of Patents in life saving drugs.

111. In the said matter i.e. ***Hoffmann-La Roche*** *[supra]*, the interim order was not passed as one of the reasons, both the Courts found, was that the suit patent was under cloud and the defendant was able to satisfy the Court by raising the credible defence. Even the suit was dismissed on these reasons. However, in the present case, both elements are missing as this Court prima facie has come to the conclusion that it is a valid patent. The defendant has failed to establish credible defence and is guilty of infringement. The facts in the present matter are entirely different than in the ***Hoffmann-La Roche*** *[supra]* case as far as merit of the case is concerned. This court otherwise is totally in agreement with the findings of two Courts on the aspect of public interest and endorses the same view.

112. Applying the said principles to the facts of the present case, it can be seen that there exists an element of public interests which require consideration in the present case. It is the plaintiffs own case that the plaintiffs patented product INDACATEROL Maleate which is subject matter of IN 222346 is quite useful and efficacious in curing COPD diseases. The plaintiff on the contrary relies upon the defendant taking the same very position before the appropriate government seeking for revocation Indian patents no IN 222346.

113. It is also noteworthy to mention that there are articles published widely in several editorial in the different years

including 2011, 2012, 2013 which have been available on record filed by the defendants showing that COPD kills more than 3 million people every year in the world. The said articles indicate that Indian Council of Medical Research also undertook a nation with asthma and COPD prevalence studies in 16 centres across India and furnished the results.

114. It is also stated that the report of National Centre for Macroeconomics and Health, the estimated economic Loss due to COPD in India is around Rs. 35000 crores (Murthy KJR, Sastry JG Economic Burden of Chronic Obstructive Pulmonary Disease: NCHH Background Papers – Burden of Disease in India 2005).

115. The articles also state that upto 84 % of the direct costs associated with COPD are due to the patient hospitalizations. The articles also goes on to state that there are several millions of population in India suffering from COPD and India being a poor country needs the treatment of the said disease with some framework and policy by the government and makers including National COPD prevention and Control Program. There are many other articles placed by the defendant on record to place these facts on record.

116. The plaintiff on the other hand controvert this position by stating that the said articles are not reflecting the genuine figures and are actually published by the defendant's own personnel. Further, it has been argued that even if it assumed that COPD is an epidemic in India, still it is not the plaintiffs

responsibility to solely cure the same and more so when the defendant's maintains that the other remedies are available to cure COPD. The plaintiff further states that it is agreeable to fulfil any demand which is pointed out to him by the defendant or anyone else. These are all disputed question of facts and there are two rival stands which are existing at this stage before the court and no conclusive opinion as to the correctness of either of them can be formed by this court at this stage.

117. I agree with the proposition that the outweighing public interest can be a compelling circumstance to consider the court to adopt alternative approach by moulding the relief and thereby fixing up royalty as against the grant of the injunction in the patent infringement cases involving medicinal preparations. The said approaches have been followed by the courts in USA while deciding the case of the parties either at the stage of the grant of the permanent injunction and the court adopts the next best alternative.

118. An alternative on the basis that the injunction can be recompensed in the terms of money by allowing the party to exploit the patent in exchange of royalty in the form of the fixing up of the royalty as against the grant of the injunction arises in the facts of any case wherein there exists ample material on record in order to enable the court to fix up the said royalty so as to appropriately recompense the plaintiff commensurately in lieu of the granting of the injunction where there exists a valid

patent and the court finds a merely that the outweighing public interests warrants the court to take the contrary view.

119. It is necessary to draw a fine distinction between the cases relating to patent infringement wherein there exists plausible ground of the invalidity of the patent coupled with the outweighing public interest enabling the court to refuse the injunction on all these grounds collectively vis a vis the cases where the patents are otherwise valid and there exists no plausible ground of the invalidity yet for serving the private commercial interests, the private defendant raises the ground of the public interests in order to harbour the infringing activities and attempts to make invention public which may have certain level of tenability in its plea depending upon the fact finding as to the correctness and veracity of the plea and other attendant circumstances.

120. This distinction is necessary as in later kind of cases where the patent is otherwise valid but the public interest is merely becoming a factor potent enough to come in its way to grant the injunction, then, the court faces a greater difficulty of performing a balancing act by finding alternatives to injunction so as to serve the public interests and simultaneously suitably recompensing the plaintiff. This is due to the reason that the statutory rights granted by sovereign to exclude others can equally not be disrespected and the inventor cannot be rendered rewardless by returning the finding of the public

interest when it is not the plaintiff to blame for enforcing its rights which are legally perfect otherwise.

121. Let me therefore ascertain as to what tools are available on record in order to enable to perform this duty of striking the balance between the parties. The said tools can be discerned from the pleas raised by the parties and position which they have taken the same can be summarized in the following manner:

a) Before starting of hearing in the injunction application in the present case, the statement was made on behalf of the plaintiffs that they are agreeable to license its patented product to the defendant subject to the defendant's agreeing that the plaintiff would allow the defendant's to import its product and work on profit sharing basis. In response thereto, the defendant refuses to consider the said offer as it is interested in conducting the manufacturing activities in India as according to the defendant that the merely importation would still lead to monopoly situation which is the ground of the tribunal to interdict for a compulsory license under Section 83 and 84 of Patent Act and upon which I cannot prematurely decide the same and perform the role of compulsory licensing tribunal at this stage without fact finding and evaluation of evidence and correctness of the stand of the parties.

b) The defendant on the other hand suggested that the court can mould the relief in its written submissions and also pleads that the court may fix up the royalty which can be ordered to be deposited before the court subject to the trial of the present suit. I find this approach again to be inequitable. This is due to the reason that in the present case, the court is not proceeding to hold that there exists a credible defence raising the grounds of the invalidity of the patent (though the defendant has raised the said grounds but the same are neither explained properly nor the same are relevant in view of the contra material on record and are distinguished by the plaintiffs for which the defendant has not provided any further answer) but is proceeding to observe on prima facie basis that there exists a valid patent and the defendant could be provided a permission to manufacture subject to payment of the royalty as an alternative to injunction so that the inventor is rewarded. Thus, the alternative to injunction approach for carrying out the activities which would otherwise be an infringement but for the public interest cannot be misunderstood on presumptive basis that the amounts are secured in the court subject to trial which means that the defendant would continue to use the invention with the plaintiff getting nothing until the trial of the suit gets concluded (without approaching

the appropriate forum which is compulsory licensing court) when prima facie case has been made out for infringement and all other circumstances warrants the injunction. That is the reason why, I cannot agree with the proposal of the defendant that this court should permit the defendant to manufacture the patented product by observing that the public interests warrants so without recompensing the plaintiff realistically at this stage and merely seeking a deposit in the court which would lead to all other generic companies would be taking the same route without actually rewarding the inventor in practice. This approach was never contemplated by the US courts nor was such jurisprudence ever intended to be laid down by this court even.

c) The third tool which exists at this stage in my hand is to fix up the royalty as an interim measure as to what sort of the royalty would be reasonable and practicable so as to suitably recompense the plaintiff as an inventor. In order to perform this task, I have gone through the records of the case. There exists sale figures of the plaintiffs and the defendant also states that it has sold 12148 unit of drug in the month of October, 2014. I find that the said material again is not adequate in order to understand the profit margin of the either side and further perform calculation on the basis of the

proximate loss or detriment to be caused to the plaintiff in terms of financial loss or otherwise in order arrive at the figure of reasonable royalty. Furthermore, the said fixation of the royalty by this court on the monthly basis would be against the scheme of the Act when there exists a mechanism under the Act to seek compulsory license and the domain of the tribunal is prescribed under the Act. Thus, it would be neither wise nor it is justifiable for me to comment on the sum of the royalty on per monthly basis or per annum basis without analyzing the relevant material on record to be presented before the court. I would say that in case the defendant was really interested in paying the royalty on practicable rates without hiding anything from the court, then the defendant ought to have proposed the concrete proposals to the court and discussions could have been made by it in detail in the written submissions as to what reasonable sum can be arrived at between the parties as an interim royalty in lieu of the injunction.

122. The grey area lies where the defendant calls upon this court to adopt alternative approach in lieu of the injunction but at the same time leaves it on the court to fix the royalty without disclosing the court the figures and concrete proposals what amount the defendant is agreeable to pay with a limited

concession of the court deposited royalty as against the payment to be released to the plaintiff. In such case, it becomes practically difficult to strike the balance between the parties and any such fixation of the royalty by the court is criticized as arbitrary and irrational. Therefore, I would refrain to adopt the third tool by fixing the royalty which is neither practicable nor desirable.

123. Having considered these three two tools which are in the nature of the alternatives available with the court to arrive at the reasonable sum of the royalty as an alternative to that of the injunction, I find that none of these alternative serve any of the purpose as the plaintiff is not recompensed as a counterbalance to the postponement of the interim injunction uptil the pendency of the trial. Therefore, these alternatives proposed by the parties are inadequate and insufficient at least at the prima facie stage to fix the interim royalty.

124. The question then arises what option is left to the court. The answer to this lies in the inbuilt scheme of the Act which is section 83 and section 84 of the Act provides for all the grounds of the public interests, public health, the patentee creating a monopoly situation by way of imports, abuse of rights and availability of the products at the reasonably affordable prices and working of the invention and the remedies including the compulsory licensing and revocation to be made by the appropriate government on this ground thereto. The defendant

has preferred some remedies and for some like compulsory licensing is not rendered remediless.

125. In such a case, if the defendant really intends to have a court aided license, then defendant is if so advised can approach the appropriate forum to urge the said grounds and the tribunal may or may not award the licensing depending upon the tenability of the pleas of the defendant. The tribunal shall also examine the reasonableness of the royalty which this court at this stage is finding it difficult to examine. Thus, in practicable terms, it is wise to relegate the defendant to approach the compulsory licensing tribunal if the public interests the sole reason for which the defendant intends to manufacture patented product with a direction that the appropriate tribunal shall decide the petition within the period of six months from the date of this order as against this court assuming the role of the licensing court when the domain of the courts and tribunals are defined. However, needless to mention here that such application for compulsory licence has to be considered as per its merit and is to be determined after hearing both parties and without any influence of my order.

126. The other alternative for the royalty fixation and working of the invention is that both the parties can mutually arrive at some terms of the licensing as stressed by the defendant for manufacturing the suit patent drug in India and agree to work upon the invention as per the rates mutually agreeable to each other. The same can be possible in close cooperation and

arriving at the suitable consensus amongst them which is not happening in the present case until date.

127. The sum and substance of the entire discussion on royalty fixation is that though this court intends to exercise the next best alternative of fixation of royalty in lieu of the injunction as an approach alternative to injunction on the premise of the public interest, but is in practice unable to exercise such option as the scheme of the Act is peculiar in nature wherein the compulsory licensing provisions are code in itself and the said tribunal can fix up the royalty properly after examining the material placed before it and examining the pleas raised before it on the public interest etc. if the case is made out within the corner of the provision. Furthermore, the material placed by the defendant and proposal provided is hardly assisting the court to arrive at sum interim sum of the royalty in lieu of the injunction payable to the plaintiff and it is more of an unreasonable and in equitable stand to merely agree for the court deposit and not the payment to the plaintiff, when as a matter of law in the case of the compulsory license, the scheme of the Act allows the payments to be made to the plaintiff as a royalty.

128. Accordingly, the court is left with no option but to state that the court cannot really switch over to the next best alternative as the same is not practically exercisable at this stage. Would that mean that public interest would be compromised by passing the interim injunction order in the case like the present one and there is no other means to strike balance. In my answer, such is

not the case. The reason is very plain and simple which is that the defendant is placing heavy reliance upon the articles/ publication by pinpointing that COPD is one of the largest epidemic in India as well as in world over. The said publications placed on record are being published in the years 2007, 2008, 2010, 2011, 2012 and 2014. All this would mean that in order to eradicate the problems of COPD, the systematic and consistent prevention programmes along with the remedies are required on continuous basis. All this would mean that it is a long drawn process to remedy and weed out COPD as an epidemic completely though it cannot be ruled out that it is curse to the society. With this thing in mind, the plaintiff has come up with the revolutionary product which the defendant is agreeable that it is highly efficacious but raises a public interests as major ground to resist the injunction by urging that the public at large is in need of the said medicine in India. The defendant does not provide any figures about the inadequacy or shortfall in the supply of the products by way of cogent and clear evidence but merely raises this ground on the strength of the figures published in the articles and publication. On the contrary, the plaintiff files an affidavit on record that the plaintiff has got the stocks ready in advance for almost two months in order to meet the demand situation and further agreeable to accelerate the supplies as soon as the demand arises. There is no contra material on record to controvert the said position except the affidavit of Dr. Ghosal filed with the written submission and after

the order was reserved which conducts some selective survey and that too does not indicate demand supply conundrum.

129. In the affidavit of Dr.Ghosal it was deposed that the medicine is not available in Meerut market and some other chemist shops. However, the same at this stage cannot be considered as the plaintiffs have got an opportunity to make their comments. The said mode of survey and credibility attached to the same has to be tested in trial but firstly the defendant has to inform the court how the demand of the product is more than that of the supply through some statistics and in which area and only then question of the shortage or non availability will be relevant, In such a case, the conditional interim order in the form of injunction can be passed uptil the decision of the application seeking compulsory licensing by the competent tribunal with a request that the decision of the compulsory licensing application can be made within the period of six months and till such time manufacturing activity of the products by the defendants can await the decision of the competent tribunal ruling on the pleas of the public interests and amongst other raised by the defendant. The Controller of Patents is bound to consider the rival versions of both parties and assess the matter on the basis of evidence and is to see as to whether the plea raised by the defendant is correct or not before forming any opinion. The defendant can file the application seeking modification of the interim order in case the decision of the compulsory licensing application is made in its

favour. I think this would sufficiently balance the rights of the parties and it would not be disservice to the public interest likewise would also not compromise the rights of the patent right holder. This balancing approach has been adopted by the court in view of the extenuating circumstances existing in the present case which is public interest so that it should not be disserved and the conditional interim order along with time bound directions can allow the parties to arrive at some workable solution for future or otherwise, the compulsory licensing tribunal shall form its opinion shortly. This is would be less prejudicial or inconvenient to the defendant as the defendant has launched the product in October 2014 and thereafter pursuant to the directions of the court, the defendant made the oral statement that the products of the defendant shall not be further floated in the market till the decision on the present application. Once, the defendant has not continued manufacturing the products, it would be wise to wait for couple of months till the decision of the compulsory licensing application to be made by the competent tribunal is decided one way or the other. After all, as per the scheme of the Act, it is compulsory licensing tribunal/ controller who has to form the opinion and terms as to licensing in case there exists a circumstances warranting tribunal aided licensing including effect on public health and issues relating to availability of the drugs at the affordable prices. Thus, the said approach is far

more viable and prudent than the approach of fixation of royalty by foreclosing the determination by the competent authority.

130. The question to be asked at this stage is whether there exists any such circumstance showing the extreme demand of the patented product in question as per the material available on record showing imminent need or dire straits reflecting the plaintiffs inability to provide the medicine in question to the consumers except the concerns emerging from articles which are noteworthy yet general in nature. I find that there is no material on record suggesting the demand of the said patented product outstripping the supplies on the basis of the public interest. Rather, there exists a contra material on record wherein the plaintiff is stated to have a surplus medicines available and agrees to further accelerate the supplies if need be.

131. **The main question in the present case before Court is whether the Court will allow a party to infringe the registered patent which is prima facie held to be valid, the infringement is established and there is no credible defence raised by the other side. The answer of this question is "NO". Under these circumstances, the Court would never encourage the infringement in view of the exclusive and statutory rights granted under section 48 of the Act. The effect of registered patent is defined in the statute and the same is not capable of being misunderstood. The statutory and monopoly rights cannot**

be reduced to a nullity as by virtue of section 48 of the Act till the term of validity of the suit patents, the plaintiff is entitled to prevent any third party who does not have its permission from the act of making, using, offering for sale, selling or importing for those purposes an infringing product in India. In the present case, the compulsory licence has not been granted by the authority to the defendant. Even its application for the same is not pending. Merely the grounds and conditions stipulated under section 83 and 84 of the Act do not absolve the defendant to infringe the registered patent.

132. Accordingly, in the facts and circumstances of the present case, the following directions are passed in order to balance the interest of the parties in the interim:

a) The defendant is restrained by itself or through its directors, group company, associates, divisions, assigns in business, licensees, franchisees, agents, distributors and dealers from using, manufacturing, importing, selling, offering for sale, exporting, directly or indirectly dealing in Active Pharmaceutical Ingredient (API), pharmaceutical products, compound or formulation containing INDACATEROL, specifically its Maleate salt, namely INDACATEROL Maleate alone or in combination with any other compound or API or in any other form as may amount to infringement of Indian Patent No.222346 of the Plaintiff No.1 until the

determination of the pleas raised by the defendant for seeking the compulsory licensing if so filed shall be determined on merit and after hearing of parties in favour of defendant, otherwise, it would continue during the pendency of the suit.

b) If such an application is filed by the defendant, under those circumstances, the directions are issued to the controller or to the relevant authority to decide the application for seeking compulsory licensing within the period of six months from the date of filing the application within two weeks from the pronouncement of the order.

c) The defendant is at the liberty to move an application seeking modification/ vacation of the interim injunction in case the application seeking compulsory licensing is decided by the competent authority in its favour or the parties otherwise arrive at some consensus on the licensing terms.

With these observations, the application, being I.A. No.24863/2014, is disposed of. It is clarified that all the findings arrived by this Court are tentative which shall have no bearing at the final stage of the suit as well as at the time of deciding the application for compulsory licence, if filed by the defendant.

I.A. No.24864/2014 (u/o XXVI R 9 CPC)

In view of the orders passed in I.A. No.24863/2014, no order is required to be passed in the present application. The same is disposed of as such.

CS(OS) 3812/2014

List the matter before the Joint Registrar on 23rd February, 2015 for completion of pleadings and admission/denial of the documents. List before Court on 2nd March, 2015 for framing of issues and directions for trial.

(MANMOHAN SINGH)
JUDGE

JANUARY 09, 2015