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IN THE HIGH COURT OF DELHI AT NEW DELHI
(Extraordinary Writ Jurisdiction)

WRIT PETITION (C) NO. OF 2015

IN THE MATTER OF A PUBLIC INTEREST LITIGATION

SHAMNAD BASHEER ... PETITIONER

VERSUS

UNION OF INDIA & OTHERS ... RESPONDENTS

INDEX

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IN THE HIGH COURT OF DELHI AT NEW DELHI

(Extraordinary Writ Jurisdiction)

WRIT PETITION (C) NO. 5590 OF 2015

IN THE MATTER OF A PUBLIC INTEREST LITIGATION

SHAMNAD BASHEER ... PETITIONER

VERSUS

UNION OF INDIA & OTHERS ... RESPONDENTS

AFFIDAVIT-IN-SUPPORT OF THE WRIT PETITION FILED ON BEHALF OF THE PETITIONER

1. That the Petitioner has filed the abovementioned Writ Petition in public interest, under Article 226 of the Constitution of India, to draw the attention of this Hon'ble Court to the gross non-compliance and irregularities in the implementation of norms pertaining to patent working disclosures mandated under the Patents Act, 1970, and has therefore sought the following reliefs:

   (1) A Writ of *Mandamus*, or any other appropriate writ or order against Respondent Nos. 2 & 3:

      i. To strictly enforce compliance with Section 146(2) read with Rule 131(1) of the Patents Act, 1970 and Rules by every Patentee and Licensee;

      ii. To initiate proceedings under Section 122(1) of the Patents Act, 1970 against errant Patentees and Licensees for non-compliance with the mandatory requirement under Section 146(2) read with Rule 131(1) of the Patents Act, 1970 and Rules;

iii. To issue notices under Section 146(1) of the Patents Act, 1970 to Patentees and Licensees to furnish true and complete information in relation to incomplete disclosure of information on commercial working of the patent;

iv. To rectify the 'comprehensive online filing services for patents' to enable Patentees and Licencees to submit full and complete working information in accordance with the Patents Act, 1970 and Rules;

v. To publish and upload the entire information relating to commercial working of all patents for all years of operation of the patent on their website as per Section 146(3) of the Patents Act, 1970 and Rules thereunder;

(2) To declare that the present format of FORM-27 as contained in Schedule II of the Patents Rules, 2003 is irrational and insufficient to sub-serve the purpose of the Patents Act, 1970;

(3) To constitute a committee of experts to suggest reforms to improve the public disclosure norms around the commercial working of patents.

2. That this Hon'ble Court on 27.05.2015 has granted permission to file the present Affidavit-in-Support of the Writ Petition to further substantiate the averments contained therein.

3. That the contents of the present Affidavit maybe treated as a part and parcel of the Writ Petition and thereby grant

such reliefs as this Hon'ble Court may deem just and appropriate in the interest of justice.

I. STATUTORY BACKGROUND

4. The Patents Act confers exclusive 'rights' to manufacture, sell and import inventions, for a period of twenty (20) years, as a reward to the inventor for disclosing new and valuable scientific or technological information useful to the public. The state sanctioned monopoly is, however, subject to a promise that the inventor will work the patented invention for the benefit of public, by ensuring that patented goods are available in adequate quantities and for a reasonable price. To this extent, the patent regime not only grants exclusive 'rights' to Patentees to prevent others from manufacturing and distributing the patented invention, but also imposes 'duties' upon them to work the invention for the public good.

5. It is reiterated that the Statement of Objects and Reasons accompanying the Patents Act, 1970 lays great emphasis on the 'duties' of the Patentees in the following words: "*patent rights are not worked to the detriment of the consumer or to the prejudice of trade or industrial development*". Furthermore, Section 83 of the Patents Act has succinctly codified the guiding principles behind the patent system as below:

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

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

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

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

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

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

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

6. To mitigate the harm that may occur due to an abuse of patent monopoly, the Patents Act confers an array of extraordinary powers upon the Respondents, to enforce the patent working requirement, including the following:

(a) The powers to issue a compulsory license, in accordance with Chapter XVI of the Act, if the Patentee has failed to enable access to the inventions at affordable prizes or to adequately meet the requirements of the public;

(b) The powers to revoke the patent, as per Section 85, if the patent has not been worked despite the grant of compulsory license;

(c) The powers to issue a compulsory license, in accordance with Section 92, in the event of national emergency or extreme urgency or to enable public non-commercial use; and

(d) The powers to issue a compulsory license, in accordance with Section 92A, to manufacture and export of patented pharmaceutical products to address public health concerns in countries with insufficient or no manufacturing capacity.

7. To this end, Section 146(1) confers powers upon Respondent Nos. 2 and 3 to require any Patentee or Licensee to furnish a statement on the extent of commercial working of their patent as and when directed to do so. More importantly, Section 146(2) imposes an express duty upon Patentees and Licensees to submit a statement on commercial working of their patent at periodic intervals, as maybe prescribed.

8. Rule 131 of Patents Rules, enacted pursuant to Section 146(2), obliges every Patentee and Licensees to disclose the true extent of commercial working of their patent, each

year, as per the format specified as 'FORM-27' under the Second Schedule to the Patents Rules. [*See* **Appendix-B at Page No. 85**] The form requires Patentees and their Licensees to disclose the following particulars:

(b) whether the patented invention has been worked on a commercial scale within India for the year in question;

(c) if the patented invention is not worked, the reasons for such non-working;

(d) if the patented invention is worked, the rights-holder must:

i. specify the quantum and value of sale of product covered by the patent in India for the relevant year in question;

ii. specify the details of licences and sub-licences granted during the relevant year;

iii. state whether the patented invention is manufactured within the territory of India in the relevant year; and

iv. state whether the public requirement of the patented invention has been met either partly or adequately or the fullest extent at a reasonable price for the relevant year;

9. Section 146(3) read with Rule 131(3) of the Patents Act further authorize Respondent No. 2 to enable public access to FORM-27 filings and other information received under Section 146.

10. More importantly, Section 122(1)(b) confers powers upon the Controller of Patents to impose penalties which may extend upto Rs. 10,00,000 (Ten Lakh Rupees) against

errant Patentees and Licensees for failure to comply with the mandate provided under Section 146 of the Patents Act and Rules.

11. Given the object and purpose of the Patents Act, it is submitted that the said information is critical for the Respondents to give complete effect to provisions on compulsory licensing and revocation of patent. Furthermore, the lack of transparent disclosure will make it impossible for honest competitors to assess their IP risks thereby stifling competition, innovation and industrial growth, and hence detrimental to public interest. This would, in turn, impact the public at large, who are denied potential access to the prospect of more affordable goods or services from competitors. The contents of the Writ Petition are reiterated and are not repeated herein for the sake of brevity.

12. As submitted in the Writ Petition, the rate and extent of compliance of FORM-27 filings by Patentees and Licensees has been abysmally low over the years. Even where Form 27s have been perfunctorily filed by patentees, it has been observed that there are several deficiencies, defects and incomplete/insufficient data in such submission. The Respondents, on the other hand, have failed to initiate any remedial or punitive action against errant patentees and licensees despite having complete knowledge such irregularities.

13. A summary of various discrepancies and irregularities observed by the Petitioner, along with illustrative references, are enumerated as below:

A. NON-COMPLIANCE

	Description	Reference
1.	30% of Patentees have failed to comply with FORM-27 filing norms between 2009 to 2012	**Annex. P-7 at Page Nos. 106**
2.	Respondents appear to have arbitrarily waived the filing requirement for Licensees	**Annex. P-12 at Page Nos. 146-47**
3.	Respondents have failed to initiate any action against Patentees and Licensees for non-compliance	**Annex. P-14 at Page Nos. 149-161**
4.	e-Filing facility of the Respondents fails to enable the Patentees to submit full and complete patent working information	**Annex. P-13 at Page No. 148**

B. DEFECTIVE COMPLIANCE

	Description	Reference
1.	Patentees have refused to disclose working information on grounds of confidentiality	**109, 333, 334**
2.	Patentees have expressed their inability to submit working information due to the nature of the invention	**223, 227, 298, 302, 374, 424, 504, 507**
3.	Patentees have left the particulars (such as quantity and value) blank	**126, 368, 369, 222, 227, 288**
4.	Patentees have not adequately explained the reasons for non-working	**225, 349, 354, 501-503, 512, 524, 526**
5.	Patentees have failed to disclose the place of manufacture of the patented product	**222, 285, 374**
6.	Patentees have claimed to have satisfied the demands of general public without any particulars	**133, 134**
7.	NATCO Pharma failed to disclose the patent working information as per the order granting compulsory license	**Annex. P-15 at Page No. 162-167**

II. NON-COMPLIANCE OF PATENT WORKING DISCLOSURES

A. Non-compliance by Patentees

14. The Annual Report the Controller of Patents (2012-13), Respondent No. 2 herein, has revealed that a vast majority of patentees have failed to comply with FORM-27 filing requirement between the years 2009 and 2012. [*See* **Annexure P-7 at Page Nos. 100-107**] The table below presents the percentage of non-compliance by Patentees from 2009 to 2012:

YEAR	PATENTS	FORM-27		% NON COMPLIANCE
		FILED	NOT FILED	
2009	37334	24009	13325	**35.69**
2010	39594	34112	5,482	**13.84**
2011	39989	27825	12,164	**30.41**
2012	43920	27946	15,974	**36.37**

B. Non-compliance by Licensees

15. The requirement under Section 146(2) read with Rule 131(2), in no uncertain terms, applies equally to Patentee and their Licensee (whether exclusive or otherwise). Despite this clear statutory obligation, it appears that Licensees have not complied with the FORM-27 filing requirement. In response to an RTI application dated 06.03.2014 [*See* **Annexure P-12(i) at Page No. 145**], the Respondents, *vide* letter dated 12.03.2014, stated that no FORM-27 was received from Licensees. [*See* **Annexure P-12(ii) at Page No. 145**]

16. More problematically, the Respondents appear to have arbitrarily exempted Licensees from complying with the FORM-27 filing requirement. The reply from the

Respondents suggests that the Section 146 mandate to disclose patent working information applies only to Patentees and not to Licensees. The relevant excerpts of the correspondence is as follows:

RTI Application dated 06.03.2014 [ANNEXURE P-12 (i)]	Reply of Respondents dated 12.03.2014 [ANNEXURE P-12 (ii)]
State the number of valid patents for which duly filled FORM-27 applications was submitted by Licensees for the years 2009 to 2012	Form 27 are filed by Patentees only, as such required information is not in possession of this authority.

17. It is humbly submitted that the waiver of patent working disclosure requirements for Licensees by Respondent authorities is unfounded, arbitrary, illegal and violative of provisions of the Patents Act and Rules.

C. Defective e-Filing Facility

18. The "Comprehensive Online Filing Services for Patents" ('**e-filing facility**') introduced by the Respondents, in 2012, meant to foster a more convenient way for Patentees and Licensees to file various forms online, including FORM-27, is wholly defective and does not adhere to the format prescribed under Schedule II of the Patents Rules. [*See* **Annexure P-13 at Page No. 148**] The online version exempts Patentees and Licensees from declaring all relevant particulars under FORM-27. In particular, the online facility does not contain any space to enter particulars pertaining to the quantum of the patented product imported or manufactured. Moreover, the e-facility does not provide an option to submit any additional information that maybe relevant for

ascertaining the working of patent, even if Patentees desire to so submit.

D. Blatant Inaction

19. Despite extensive knowledge of the blatant and widespread contravention of Section 146 of the Patents Act, the Respondent No. 2 has failed to initiate any action against errant Patentees and their Licensees. In response to an RTI application filed by the Petitioner, pertaining to certain pharmaceutical inventions, the Respondents categorically admitted that no action has been taken against any Patentee or Licensee for non-compliance with the FORM-27 disclosure mandate. [*See* **Annexure P-14 (Colly) at Page Nos. 149-161**]

20. It is submitted that the failure of the Respondents to initiate proceeding against errant Patentees and Licensees under Section 122 for non-filing filing of FORM-27s is arbitrary, illegal, and a gross dereliction of a public duty.

21. More egregiously, the Respondent No. 2 has disregarded it's own order dated 09.03.2012 in C.L.A No. 1 of 2011, wherein it had granted India's first post TRIPS compulsory licence in favour of NATCO Pharma Ltd., a reputed generic pharmaceutical company. The compulsory licence, was in respect of *Sorefanib Tosylate*, an excessively priced anti-cancer drug (*Nexavar*®) patented by Bayer Corporation (Patent No. IN21578). While granting the licence, the Respondent No. 2 imposed several conditions on the licensee (NATCO), including an obligation to account for the sales of the licensed patented drug on a quarterly basis.

22. In a letter dated 12.02.2014, [*See* **Annexure P-15(ii) at Page Nos. 164**] and 06.02.2015 [*See* **Annexure P-15(iv) at Page Nos. 167**] the Respondents stated that NATCO had not submitted this information, in relation to an RTI request dated 10.02.2014 [*See* **Annexure P-15(i) at Page Nos. 162-163**] and 19.01.2015 [*See* **Annexure P-15(iii) at Page Nos. 165-166**]. Furthermore, the Respondents have admitted that no action has been taken against NATCO for this blatant contravention of an important licensing condition.

23. The inaction of Respondents against this flagrant violation of working disclosure norms by patent right-holders is illegal and arbitrary and a gross dereliction of their public statutory duty. It enables patent holders to evade public scrutiny of the manner in which they have used or abused a statutorily granted monopoly, and frustrates an important rationale underlying the patent system and the social bargain inherent within.

24. The inaction by Respondents also seriously prejudices the citizens' right to know as to how patents are serving the public interest. Unless concrete action is taken, Patentees will have no incentive to comply with an important statutory obligation. It is submitted that Patentees are often loathe to provide working information voluntarily and it is only the threat of statutory sanction that will compel them to do so. This is amply illustrated in the Petitioner's own case, wherein a detailed set of questions were addressed to Bayer Corporation in relation to its patented anti-cancer drug (*Nexavar*®) seeking clarifications on their FORM-27 filings. These clarifications were absolutely necessary as the Petitioner found several inconsistencies, gaps and errors in their submissions.

However, Bayer Corporation refused to comment on the issue, initially citing that the matter was *sub-judice* and later on simply refusing to respond on the apparent ground that other litigations were pending. The Petitioner published a detailed summary of the investigations, including various communications addressed to Bayer Corporation in a report titled *'Bayer's Nexavar and the 'Working' of Compulsory Licensing: Mind the Patent (Information) Gap!'*. [*See* **Annexure P-16 at Page Nos. 168-205**]

III. LIMITED PUBLIC ACCESS TO PATENT WORKING INFORMATION

25. Section 146(3) read with Rule 131(3) envisages the Controller of Patents, Respondent No. 2 herein, to enable public access to FORM-27 filings. In a laudatory move, Respondent No. 2 has enabled free public access to FORM-27 filings in an online searchable database. [*See* **Annexure P-3 at Page No. 85**] The said database is, however, significantly limited as it contains the FORM-27 filings pertaining to the calendar year 2012 and 2013 alone, and not prior years (i.e. 2003 to 2011).

26. Given the importance of patent working information, it is submitted that the statutory requirement of publication is *mandatory* in nature. The lack of transparent disclosure will make it impossible for honest competitors to assess their IP risks thereby stifling competition, innovation and industrial growth, and hence detrimental to public interest. This would in turn impact the public at large, who are denied potential access to the prospect of more affordable goods or services from competitors.

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IV. WIDESPREAD DEFECTIVE COMPLIANCE

27. The Petitioner along with his Research Associates ('RAs'), have carefully examined the FORM-27 filings obtained from Respondent Nos. 2 and 3 under the RTI Act and from the aforesaid database. The Petitioner primarily examined FORM-27 filings in relation to the following three critical sectors:

    (i) pharmaceutical drugs (particularly life-saving drugs for fatal diseases such as Cancer, AIDS, Diabetes and Hepatitis)
    (ii) information and telecommunication technology and;
    (iii) inventions stemming from public sponsored research and development. ('R&D').

28. Given the enormous number of patents that are currently valid, the Petitioner limited the surveyed 270 FORM-27 filings relating to 143 major patents across the three sectors (above). [*See* **Annexure P-4 at Page Nos. 87-94**] It is submitted that the survey has revealed a significant number of defective declarations by Patentees. Many submissions were found to be grossly incomplete, incomprehensible or inaccurate. A brief summary of the nature of defects observed by the Petitioner are detailed below.

A. Refusal to Declare

29. The Petitioner noticed that certain Patentees have refused to declare the particulars contained in FORM-27 on the grounds of '*confidentiality*'. For example, Ericsson Inc., a telecom giant, has refused to disclose patent working information to the public under the alleged veil of trade

secrecy. The relevant FORM-27 filings by them state that: *"as all the licenses are confidential in nature, the details pertaining to the same shall be provided under specific directions from the Patent Office."* [*See* **Annexure P-9 at Page Nos. 124-132**] It bears noting that the FORM-27 filings for eight (8) of their patents investigated by the Petitioner are currently subject to anti-competitive investigations by the Competition Commission of India ('CCI'). In another instance, FORM-27 filing in relation to *ViraferonPeg*, a breakthrough Hepatitis C injection patented by Merck Sharp & Dohme Corp., a major pharmaceutical company, stated that *"item requests information that is confidential and sensitive business information and thus we provide only approximate information ..."* and further stated that *"the patentee humbly request leave to submit such details on a confidential basis in a sealed cover so that access to our competitors is denied."* [*See* **Annexure P-18 at Page Nos. 333-334**]

30. It is submitted that the obligation on the Patentees to declare patent working information as per FORM-27 is *mandatory*. It is denied that the said information can be deemed to be *confidential* or in any manner detrimental to the patent holders. Therefore, the refusal to declare commercial working information is illegal and liable for punishment as per Section 122 of the Patents Act.

B. Inability to Submit

31. Several Patentees in the telecom sector have expressed their inability to disclose information pertaining to quantum and value of the patented product due to the *nature* of the invention. Illustratively, Motorola Mobility Inc. in relation to Patent No. 239197 stated that: *"Due to the*

nature of invention, it is not possible to determine the quantum and value of the above patented product or process." It is respectfully submitted that such statements appear to fly in the face of industry practice, given that Patentees in this sector usually license their patents on Fair, Reasonable and Non-Discriminatory ('**FRAND**') terms to competitors. In a majority of licensing agreements, the Patentees typically insist on the right to audit the sales and revenues of their licensees' products, so as to foster an accurate reporting and payment of royalties.

32. Therefore, it appears that there is a strong likelihood that some of these omissions are deliberate, with a view to escape public scrutiny of working of patents. As such, the alleged difficulty in disclosing the quantum and value of products that comprise the patent may not comport with the reality of business practices and does not amount to an insurmountable hurdle. Nonetheless, it is humbly submitted that the statutory mandate under Section 146 must be complied with.

C. Failure to explain Non-Working

33. If the patent has not been worked in a certain year, the FORM-27 requires the Patentees to provide reasons for such non-working and the steps being taken to redress this non-working. Over 65% (i.e., 28 out of 42) of such FORM-27 filings either failed to address this query or provide a satisfactory explanation thereof. A small fraction of patentees have callously ignored this question and left the column blank. The following table contains the names of the Patentees and their corresponding number of

FORM-27 filings which have failed to explain the reasons for non-working is as under:

Sector	FORM-27s
Pharmaceutical	**10**
Allergan Inc	2
Bayer Corporation	3
Bristol-Myers Squibb	2
Merck Sharp & Dohme Corp.	1
Novartis AG	2
Telecommunications	**3**
Samsung Electronics Co. Ltd.	3
Public Financed Research	**15**
CSIR	6
Department of Biotechnology	4
IITs	5
TOTAL	**28**

D. Blank Submissions

34. Close to half of all submissions (40% approximately) surveyed failed to disclose either the value or quantity of their patented products. Many of such Patentees have left the relevant particular blank. Illustratively, in a FORM-27 filed in 2010 by Bayer, it does not indicate the value of the 4665 units that were imported in 2009. This column was left blank by the Patentee. [*See* **Annexure P-9 at Page Nos. 124-132**] Few patentees even went to the extent of flippantly stating that: *"information not readily available. Information will be provided if asked for"*. The following table contains the names of Patentees and their corresponding number of FORM-27 filings which have failed to disclose either the value or quantity of their patented product:

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Sector	Undisclosed Value	Undisclosed Quantity
Pharmaceutical	**11**	**13**
Allergan Inc	2	2
Astrazenca AB	3	3
Bayer Corporation	1	-
Bristol-Myers Squibb	0	6
F. Hoffmann-LA-Roche AG	2	2
Pfizer Products Inc.	2	-
Pharmacacia & Upjohn Co.	2	-
Telecommunications	**60**	**58**
Apple Inc.	1	1
Ericsson Inc.	16*	16
Motorola Inc.	13	13
Nokia Corporation	18	18
Research In Motion	7	7
Samsung Electronics Co.	3	3
Public Funded Research	**13**	**8**
CSIR	9	3
Department of Biotechnology	2	3
IITs	2	2
TOTAL	**84**	**79**

** Patentee has provided overall figures instead of the patent(s) in question*

E. Overall Sales

35. The FORM-27 filings provided by Ericsson Inc. contains the overall sales of the company, instead of limiting it to the specific patented product in question, thereby making it impossible to gauge the precise extent of working of the patent in question. [*See* **Annexure P-9 at Page Nos. 124-132**]

F. Indeterminate Quantity of the Product

36. The FORM-27 requires the Patentees to declare the quantity of the patented product, either manufactured or imported. A vast majority of the FORM-27 filings (close to 60% approximately) have provided the import or sales figures in vague or indeterminate units of measurement, thereby preventing a fair assessment of the quantum of working. Illustratively, a perusal of FORM-27 filed in relation to *Nexavar*® (Patent No. IN21578) [*See* **Annexure P-9 at Page No. 125-126**] for the year 2009 by Bayer Corporation stated that 4665 units of the drug were imported and 1679 units of the drug were sold. But it does not indicate the number of tablets contained in each of 4665/1679 units. Nor does it indicate the number of such units required by each patient per month. The following table contains the names of Patentees and their corresponding number of FORM-27 submissions which have failed to indicate the precise quantity of their patented product:

Sector	**FORM-27s**
Pharmaceutical	**71**
Allergan Inc	5
Astrazenca AB	13
Bayer Corporation	1
Bristol-Myers Squibb	11
F. Hoffmann-LA-Roche AG	4
Genentech Inc	5
Glaxo Group Limited	7
Merck Sharp & Dohme Corp.	4
Novartis AG	9
Pfizer Products Inc.	5
Pharmacacia & Upjohn Co.	7
TOTAL	**71**

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G. Place of manufacture

37. FORM-27 requires Patentees to specify the quantity and value of patented invention manufactured in India. If the product is imported, the Patentee must provide country-wise details of the quantity and value of import. 109 out of 217 (approximately 50%) FORM-27 filings that claimed to have worked the patent did not indicate the place of manufacture of the patented invention. The following table contains the Patentee-wise FORM-27 submissions which have failed to indicate the place of manufacture of the patented product:

Sector	FORM-27s
Pharmaceutical	27
Allergan Inc	7
Astrazenca AB	6
Bristol-Myers Squibb	8
F. Hoffmann-LA-Roche AG	4
Genentech Inc	2
Telecommunications	74
Apple Inc.	1
Ericsson Inc.	16
Motorola Inc.	12
Nokia Corporation	18
Qualcomm Inc.	17
Research In Motion	7
Samsung Electronics Co. Ltd.	3
Public Financed Research	8
CSIR	7
Department of Biotechnology	1
TOTAL	**109**

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H. Licensing information

38. FORM-27 requires patentees to furnish all available details relating to licences and sub-licences granted during the concerned year. One third of the FORM-27 filings failed to even indicate whether any license was granted during the year. Moreover, close to half of them which indicated to have licensed their patent did not disclose any details of their Licensees. The following table contains the Patentee-wise FORM-27 submissions which have failed to provide licensing related information:

Sector	Undisclosed Licenses	Undisclosed Licensees
Pharmaceutical	**46**	0
Allergan Inc	1	-
Astrazenca AB	4	-
Bayer Corporation	4	-
Bristol-Myers Squibb	11	-
F. Hoffmann-LA-Roche AG	2	-
Genentech Inc	2	-
Glaxo Group Limited	1	-
Novartis AG	8	-
Pfizer Products Inc.	6	-
Pharmacacia & Upjohn Co.	7	-
Telecommunications	**31**	**26**
Ericsson Inc.	16*	-
Motorola Inc.	4	9
Nokia Corporation	3	17
Research In Motion	7	-
Samsung Electronics Co.	1	-
Public Funded Research	**12**	**7**
CSIR	11	0
Department of Biotechnology	1	0
IITs	0	2
Indian Institute for Science	0	5

TOTAL	**89**	**33**

** Patentee has refused to disclose the details of licensee on the basis of confidentiality.*

I. Reasonable Requirements of the Public

39. If the patent has worked in a particular year, the FORM-27 requires the Patentee to indicate whether or not the reasonable requirement of public have been met, either partly, adequately or to the fullest extent, at a reasonable price. A vast majority of FORM-27 filings indicated that public requirements have been met, but failed to provide any factual data or evidence in support of such assertions. At least three Patentees claimed that they met this requirement through their various Patient Assistance Programs ('**PAPs**'). These Patentees, however, failed to disclose the specific extent of assistance provided to patients. Illustratively, the FORM-27 declaration filed in relation to Patent No. IN21578 covering *Nexavar*® (an anti-cancer drug) by Bayer Corporation for the year 2011, claimed that the reasonable requirement of public had been meet to the fullest extent. However, the Respondents found the exact opposite and went on to grant a compulsory licence over this patented drug in favour of NATCO, on the ground that the drug sold by the patentee was far too expensive and only 2% of the patient population had access to it. This finding has attained finality, with the Hon'ble Supreme Court of India upholding the grant of compulsory licence by the IPO *vide* Order dated 12.12.2014 [S.L.P (c) No. 30145 of 2014].

J. Value of sales in foreign denomination

40. FORM-27 requires the Patentees to provide the value of their patented products, (either imported or manufactured

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in India), in terms of Indian National Rupee ('INR'). The survey revealed four (4) FORM-27 declarations containing the amount in currencies other than INR, and that too, without specifying the rate of conversion.

Sector	FORM-27s
Pharmaceutical	**4**
Astrazenca AB	2
Bristol-Myers Squibb	1
Glaxo Group Limited	1
IRBM Science Part S.p.A	0
TOTAL	**4**

41. The following table contains a summary of Petitioner's findings on defective declarations by patentees:

NATURE OF DEFECTS		TOTAL	
		F-27s	%
QUANTITY	Undisclosed	79	38.3
	Indeterminate Units	71	58.1
VALUE	Undisclosed	84	38.3
	Foreign Denomination	4	0.1
MANUFACTURE	Location Undisclosed	109	50.3
LICENSING INFORMATION	Undisclosed	89	33.5
	Undisclosed Details	33	50.4
NON-WORKING	Reasons Undisclosed	28	66.7

42. It is submitted that the defective disclosures make a mockery of an important statutory obligation enshrined in Section 146 and Rule 131 of the Patents Act. If this practice is allowed to continue, the entire objective behind the working requirement stands defeated, thereby causing prejudice to innovation imperatives and the right of the public in ensuring that the patent is being worked for their benefit.

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V. DEFECTS IN FORM-27 FORMAT

43. The Petitioner humbly submits that the current format of FORM-27 is irrational and patently insufficient inasmuch it fails to fulfil the purpose sought to be achieved by the Patents Act. The present version of FORM-27 is vaguely worded and fails to call for a number of important particulars relating to the working of patents. Some of the glaring defects are highlighted below:

(1) The operative portion of the FORM-27 vaguely requires the patentees and licensees to *"give whatever details are available"* pertaining to patent working information. It is submitted the present wording has permitted the Patentees and Licensees to arbitrarily exclude pertinent information or provide vague information.

(2) Paragraph 3(i)(b) of the current FORM-27 fails to capture the actual sale of the patented invention in India. For it is not clear what is meant by "value" of the product. Furthermore, the present format is insufficient to assess the extent to which the patented invention or product is able to meet the reasonable requirement of public. When it comes to patented drugs, for instance, it is necessary to know the required dosage per patient to effectively assess as to how many patients are being served through the supply of the patented product.

(3) Paragraph 3(ii)(b) of the current FORM-27 vaguely requires Patentees to disclose licensing information. The form states: *"give whatever details are available: the licences and sub-licences granted during the year."* Due

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to the lack of precision, a number of submissions do not adequately disclose details of licensees or licensing arrangements. Therefore, in order to make for a more effective assessment, this provision ought to clearly ask whether the patent has been licenced in the first place; if so, it must then call for more elaborate details, such as the names of licensees, broad terms of licence, whether products are being manufactured under the licence, whether such licenses are exclusive or not.

(4) The FORM-27 declaration merely requires Patentees to state whether or not the reasonable requirement of the invention to the public have been met. However, this vague and broad question is irrational, since it is likely to be met with only one standard response from all patentees, namely that they are satisfying the reasonable requirements of the public. One is hard pressed to think of any Patentee that would state otherwise, and our FORM-27 investigations do not disclose a single filing that states so. Instead, the FORM-27 declaration ought to call for specific information that would enable independent assessment on whether the reasonable requirement of patented invention has been met. Illustratively, the declaration should extract the following:

i) estimated demand of the patented invention or product;

ii) extent to which the demand has been met (i.e., availability);

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iii) details of any special schemes or steps undertaken by the patentee to satisfy the demand.

(5) Few patentees have stated that the reasonable requirements of the public are met through Patient Assistance Programs ('**PAPs**'). However, they fail to disclose the extent of such assistance actually provided to patients.

(6) In the high technology sector, the same patent can be deployed in multiple products or technologies and therefore the working requirement should capture all of these potential manifestations of the patent. In all such cases, the Patentee must be made to disclose all of the technologies, applications and products where the patent is so deployed or used. Since the current FORM-27s do not call specifically for this information, patentees typically disclose only one application or product.

(7) Conversely, it is often the case with telecommunications and other technology sectors, that one product may contain multiple patents underlying it. Therefore, it is critical that the working disclosure norms require the rights-holder to furnish a complete list of patents and patent applications covering that particular technological product. Illustratively, if Siemens owns the patents covering the CDMA technology (a technology standard), it ought to disclose all related patents in each of the FORM-27 filings relating to the various patents covering CDMA technology. In short, every

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patentee that holds multiple patents that cover a single product must disclose other "related" patents in their FORM-27 for each such patent. A failure to disclose such information adversely impacts innovation and competitors significantly, as it unduly increases their search costs in all cases where there are potentially multiple patents covering the same product.

44. In a nutshell, it is submitted that the information necessary for the Respondent authorities to effectively monitor the working of patents must contain such particulars as would enable one to determine whether or not the patented invention is satisfying the reasonable requirements of the public (through supply in adequate quantities as well as at a reasonably affordable price to the public). This information is absolutely critical for triggering the compulsory licensing and revocation provisions and thereby ensuring that the public at large have the potential to access affordable medications.

45. The lack of access to patent working information directly impacts the possibility of such trigger and denies consumers and the wider public the potential to access more affordable patented technologies, a concern most starkly felt in the area of patented medicines and public health.

FILED BY:

Date : 03.07.2015
Place : New Delhi

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IN THE HIGH COURT OF DELHI AT NEW DELHI
(Extraordinary Writ Jurisdiction)

WRIT PETITION (C) NO. OF 2015

IN THE MATTER OF A PUBLIC INTEREST LITIGATION

SHAMNAD BASHEER ... PETITIONER

VERSUS

UNION OF INDIA & OTHERS ... RESPONDENTS

AFFIDAVIT

I, Shamnad Basheer, son of Mr. M. M. Basheer, aged about 38 years, resident of "Nishad", Kulathupuzha, Quilon District, Kerala – 691 310, having office at IDIA Charitable Trust, C/o. Spire, No. 45, 2nd Floor, Jubilee Building, Museum Road, Bangalore – 560 025, presently in New Delhi, do hereby solemnly affirm and state as follows:

1. That I filed the present petition as a Public Interest Litigation.

2. That I am Petitioner in the abovementioned matter and am conversant with facts and circumstances of the case and as such am competent to swear the present affidavit filed in support of the Writ Petition.

3. That the contents of Paragraph Nos. 1 to 45 of the present affidavit are facts true to my knowledge and are based upon legal advice received by me from the Advocate and believed to be true and correct.

DEPONENT

VERIFICATION

I, the above named Deponent, do hereby solemnly affirm and verify that the contents of this affidavit are true to best of my knowledge and belief and nothing material has been concealed therefrom.

Verified on this the 27 day of July, 2015 at New Delhi.

DEPONENT

Supreme Court The Seal of the Oath Commissioner Sl. No. 26/2015 ANIL KUMAR JHA Appt. by Delhi High Court Period 25-03-2015

I identified the deponent who has signed in my presence. 28/7/2015

CERTIFIED THAT THE DEPONENT Shri/Smt. M. M. Basheer S/o, W/o, D/o Kulathupuzha, Kerala has understood the contents of the affidavit which have been read & explained to me are true and correct to his knowledge. 27.7.15

Oath Commissioner Delhi