

UNION OF INDIA

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v.

INDIAN RADIOLOGICAL AND IMAGING
ASSOCIATION AND ORS. ETC. ETC.

(I.A. Nos. 13-15 of 2017)

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IN

(Special Leave Petition (C) Nos. 16657-16659 of 2016)

MARCH 14, 2018

**[DIPAK MISRA, CJI, A. M. KHANWILKAR AND
DR. D.Y. CHANDRACHUD, JJ.]**

C

*Pre-Conception and Pre-Natal Diagnostic Techniques
(Prohibition of Sex Determination) Act, 1994:*

s. 32(1) and (2), and ss. 4, 5 and 6 – Writ Petition before High Court challenging r. 3.3 (1)(b) of PCPNDT Rules, 1996 and r. 6 of PCPNDT Six Months Training Rules, 2014 – High Court held that there is absence of provision under the Act empowering any of the bodies or the Central Government to prescribe qualifications for practicing medicine with the aid of an ultrasound imaging equipment or to prescribe nature and content of the curriculum or duration of the qualification – Appeal to Supreme Court – Application seeking stay of order of High Court – Held: s. 32(1) confers rule-making power upon Central Government for “carrying out the provisions of the Act” and to specify minimum qualification for persons to be employed at genetic counselling centres, laboratories and clinics – Parliament which has unquestioned authority and legislative competence to frame the law, considered it necessary to empower the Central Government to frame Rules to govern the qualification of persons employed in genetic counselling centres, laboratories and clinics – Wisdom of the competent legislature in adopting the policy cannot be substituted by the Court in exercise of power of judicial review – The Training Rules, 2014 were made by the Central Government in exercise of the power conferred by Parliament – Specification of qualifications should be read in a purposive sense which will fulfill the object of law – Even on a plain and natural construction of the words used by

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- A *Parliament, specification of qualifications must necessarily comprehend the power to prescribe training – The rationale is that the training would sensitize the person of the legislation which has been enacted to deal with a serious social evil and be conscious of the misuse of sex-selection tests – Pre-natal diagnostic procedures are also susceptible to grave misuse – Prima facie the Rules are*
- B *neither ultra vires the parent legislation nor do they suffer from manifest arbitrariness – The judgment of the High Court also squarely impinges upon the directions issued by Supreme Court in*
- C **Voluntary Health Association case – Therefore, judgment of the High Court needs to be stayed during pendency of the proceedings of the case – It is directed that*
- D **Voluntary Health Association case to be strictly enforced by all the States and Union Territories untrammelled by any other court – Pre-Natal Diagnostic Techniques s (Regulation and Prevention of Misuse) Rules, 1996 – r. 3.3(1)(b) – Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014 – s. 6.*

**Voluntary Health Association of Punjab v. Union of India (2016) 10 SCC 265 : [2016] 8 SCR 192 – referred to.*

Case Law Reference

- E **[2016] 8 SCR 192 referred to Para 2**
- CIVIL APPELLATE JURISDICTION : I.A Nos. 13-15 of 2017 in Special Leave Petition (C) Nos. 16657-16659 of 2016.
- From the Judgment and Order dated 17.02.2016 of the High Court of Delhi at New Delhi in W. P. (C) No. 6968 of 2011, W. P. (C) No. 2721 of 2014 and W.P. (C) No. 3184 of 2014 respectively.
- F Ms. Pinky Anand, ASG, Vikas Singh, Colin Gonsalves, Dr. Ashwini Kumar, Arvind P. Datar, Sr. Advs., S. Venkatesh, Varun Singh, Somesh Srivastava, Vikas Maini, Lakshmi Raman Singh, Ms. Anitha Shenoy, Ms. Aditi Saxena, Ms. Jyoti Mendiratta, Aruneshwar Gupta, Varun Dewan, Gopal Singh, Manish Kumar, Mohan Prasad Gupta, Ms. Asha G. Nair, S.S. Rawat, Ms. Binu Tamta, Ms. Sunita Sharma, S.W.A. Qadri, Rajesh Ranjan, Ms. Snidha Mehra, Zaid Ali, G.S. Makker, B.V. Balaramdas, Ms. Rashmi Nandakumar, Raushan Tara Jaswal, K. G. Gopalakrishnan, S. R. Raghunathan, S. Santanam
- G Swaminadhan, Mrs. Aarthi Rajan, Ms. Nishtha Khurana, Varun Pandey,
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Dinkar Kalra, Aruneshwar Gupta, Pramod Dayal, B. V. Balaram Das, Gurmeet Singh Makker, Gagan Gupta, Zoheb Hussain, Smarhar Singh, Keshav Mohan, Advs. for the appearing parties. A

The following Order of the Court was delivered:

ORDER

1. We have heard learned counsel for the contesting parties and considered the written submissions tendered, for the purpose of evaluating the grant of interim relief. B

2. In **Voluntary Health Association of Punjab v Union of India**¹, this Court by a judgment dated 8 November 2016 issued comprehensive directions for the purpose of effective implementation of the provisions of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994². The directions issued by this Court are extracted below: C

“33. Keeping in view the deliberations made from time to time and regard being had to the purpose of the Act and the far reaching impact of the problem, we think it appropriate to issue the following directions in addition to the directions issued in the earlier order:- D

(a) All the States and the Union Territories in India shall maintain a centralized database of civil registration records from all registration units so that information can be made available from the website regarding the number of boys and girls being born. E

(b) The information that shall be displayed on the website shall contain the birth information for each District, Municipality, Corporation or Gram Panchayat so that a visual comparison of boys and girls born can be immediately seen. F

(c) The statutory authorities if not constituted as envisaged under the Act shall be constituted forthwith and the competent authorities shall take steps for their constitution of the statutory bodies so that they can become immediately functional after expiry of the term. That apart, they shall meet regularly so that the provisions of the Act can be implemented in reality and the effectiveness of the legislation is felt and realized in the society. G

¹Writ Petition (c) No. 349 of 2006

²PCPNDT Act

- A (d) The provisions contained in Sections 22 and 23 shall be strictly adhered to. Section 23(2) shall be duly complied with and it shall be reported by the authorities so that the State Medical Council takes necessary action after the intimation is given under the said provision. The Appropriate Authorities who have been appointed under Section 17(1) and 17(2) shall be imparted periodical training to carry out the functions as required under various provisions of the Act.
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- (e) If there has been violation of any of the provisions of the Act or the Rules, proper action has to be taken by the authorities under the Act so that the legally inapposite acts are immediately curbed.
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- (f) The Courts which deal with the complaints under the Act shall be fast tracked and the concerned High Courts shall issue appropriate directions in that regard.
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- (g) The judicial officers who are to deal with these cases under the Act shall be periodically imparted training in the Judicial Academies or Training Institutes, as the case may be, so that they can be sensitive and develop the requisite sensitivity as projected in the objects and reasons of the Act and its various provisions and in view of the need of the society.
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- (h) The Director of Prosecution or, if the said post is not there, the Legal Remembrancer or the Law Secretary shall take stock of things with regard to the lodging of prosecution so that the purpose of the Act is subserved.
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- (I) The Courts that deal with the complaints under the Act shall deal with the matters in promptitude and submit the quarterly report to the High Courts through the concerned Sessions and District Judge.
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- (j) The learned Chief Justices of each of the High Courts in the country are requested to constitute a Committee of three Judges that can periodically oversee the progress of the cases.
- (k) The awareness campaigns with regard to the provisions of the Act as well as the social awareness shall be undertaken as per the direction No.9.8 in the order dated March 4,2013 passed in Voluntary Health Association of Punjab (supra).
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- (l) The State Legal Services Authorities of the States shall give emphasis on this campaign during the spread of legal aid and involve the para-legal volunteers. A
- (m) The Union of India and the States shall see to it that appropriate directions are issued to the authorities of All India Radio and Doordarshan functioning in various States to give wide publicity pertaining to the saving of the girl child and the grave dangers the society shall face because of female foeticide. B
- (n) All the appropriate authorities including the States and districts notified under the Act shall submit quarterly progress report to the Government of India through the State Government and maintain Form H for keeping the information of all registrations readily available as per sub-rule 6 of Rule 18A of the Rules. C
- (o) The States and Union Territories shall implement the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014 forthwith considering that the training provided therein is imperative for realising the objects and purpose of this Act. D
- (p) As the Union of India and some States framed incentive schemes for the girl child, the States that have not framed such schemes, may introduce such schemes.”(Emphasis supplied) E

3. The PCPNDT Act was enacted by Parliament, as its Preamble indicates, to prohibit sex-selection, and to regulate pre-natal diagnostic techniques so as to prevent their misuse for sex determination. The Preamble reads thus:

“An Act to provide for the regulation of the use of pre-natal diagnostic techniques for the purpose of detecting genetic or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex linked disorders and for the prevention of the misuse of such techniques for the purpose of pre-natal sex determination leading to female foeticide; and, for matters connected there with or incidental thereto.” F
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4. The intent of Parliament in enacting the law is clarified in the Statement of Objects and Reasons which accompanied the introduction of the Bill. Insofar as it is material to the present controversy, the Statement of Objects and Reasons reads thus:

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A “Introduction:

B In the recent past Pre-natal Diagnostic Centres sprang up in the urban areas of the country using pre-natal diagnostic techniques for determination of sex of the foetus. Such centres became very popular and their growth was tremendous as the female child is not welcomed with open arms in most of the Indian families. The result was that such centres became centres of female foeticide. Such abuse of the technique is against the female sex and affects the dignity and status of women. Various Organisation working for the welfare and uplift of the women raised their heads against such an abuse.”

C Statement of Objects and Reasons

D It is proposed to prohibit pre-natal diagnostic techniques for determination of sex of the foetus leading to female foeticide. Such abuse of techniques is determination against the female sex and affects the dignity and status of women. A legislation is required to regulate the use of such techniques and to provide deterrent punishment to stop such inhuman act.

E The Bill, *inter alia* provides for:-

- F (i) prohibition of the misuse of pre-natal diagnostic techniques for determination of sex of foetus, leading to female foeticide;
- (ii) prohibition of advertisement of pre-natal diagnostic techniques for detection or determination of sex;
- G (iii) permission and regulation of the use of pre-natal diagnostic techniques for the purpose of detection of specific genetic abnormalities or disorders;
- (iv) permitting the use of such techniques only under certain conditions by the registered institutions; and
- (v) punishment for violation of the provisions of the proposed legislation.

H 2. The Bill seeks to achieve the above objectives.”

5. The comprehensive directions issued by this Court in its decision in **Voluntary Health Association of Punjab (Supra)** must be read as integral to the enforcement of a law which has been enacted by Parliament to curb a grave social evil and to render the statutory provisions truly effective to curb the mischief which was sought to be addressed by enacting the law. More specifically, in its judgment dated 8 November 2016, this Court has required the states and the Union territories to implement the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014 forthwith. The decision explains that the provision for training required under the above subordinate legislation, is imperative to realise the objects and purposes of the Act.

6. The impact of the directions which have been issued by this Court is negated by a judgment rendered by a Division Bench of the Delhi High Court on 17 February 2016 in a batch of cases including **Indian Radiological and Imaging Association (IRIA) v Union of India**³, **Indian Medical Association v Union of India**⁴ and **Sonological Society of India v Union of India**⁵. Before the Delhi High Court, there was a challenge to the provisions of Rule 3(3)(1)(b) of the PCPNDT Rules, 1996 and Rule 6 of the Six Months Training Rules as amended by a notification dated 9 January 2014. Rule 3.3(1)(b), which was in challenge reads as follows:

“3.3(1) Any person having adequate space and being or employing....

(a)...

(b)...a Sonologist, Imaging Specialist, Radiologist or Registered Medical Practitioner having Post Graduate degree or diploma or six months training duly imparted in the manner prescribed in the “the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014.”

Rule 6 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014 is in the following terms:

³Writ Petition (C) No. 6968 of 2011

⁴Writ Petition (C) No. 2721 of 2014

⁵Writ Petition (C) No. 3184 of 2014

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A “6. Eligibility for training.-

(1) Any registered medical practitioner shall be eligible for undertaking the said six months training.

B (2) The existing registered medical practitioners, who are conducting ultrasound procedures in a Genetic Clinic or Ultrasound Clinic or Imaging Centre on the basis of one year experience or six months training are exempted from undertaking the said training provided they are able to qualify the competency based assessment specified in Schedule II and in case of failure to clear the said competency based exam, they shall be required to undertake the complete six months training, as provided under these rules, for the purpose of renewal of registrations.”

C Rule 6(2) provides for an exemption to existing registered medical practitioners conducting ultrasound procedures in a genetic or ultrasound clinic or imaging centre subject to qualifying in the competency based assessment.

D 7. The Delhi High Court has *inter alia* held that it was unable to find any provision in the PCPNDT Act empowering any of the bodies constituted under the law or even the Central government to prescribe qualifications for practicing medicine with the aid of an ultrasound imaging equipment or to prescribe the nature and content of the curriculum or duration of the qualification. While disposing of the batch of writ petitions, the Delhi High Court has issued the following directions:

E (i) “that Section 2(p) of the PNDT Act defining a Sonologist or Imaging Specialist, is bad to the extent it includes persons possessing a postgraduate qualification in ultrasonography or imaging techniques – because there is no such qualification recognized by MCI and the PNDT Act does not empower the statutory bodies constituted thereunder or the Central Government to devise and coin new qualification;

F (ii) We hold that all places including vehicles where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or has the potential of detection of sex during pregnancy or selection of sex before conception, require registration under the Act;

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- (iii) However, if the person seeking registration (a) makes a declaration in the form to be prescribed by the Central Supervisory Board to the effect that the said machine or equipment is not intended for conducting pre-natal diagnostic procedures; (b) gives an undertaking to not use or allow the use of the same for pre-natal diagnostic procedures; and, (c) has a “silent observer” or any other equipment installed on the ultrasound machines, as may be prescribed by the Central Supervisory Board, capable of storing images of each sonography tests done therewith, such person would be exempt from complying with the provisions of the Act and the Rules with respect to Genetic Clinics, Genetic Laboratory or Genetic Counselling Centres; A B C
- (iv) If however for any technical reasons, the Central Supervisory Board is of the view that such “silent observer” cannot be installed or would not serve the purpose, then the Central Supervisory Board would prescribe other conditions which such registrant would require to fulfil, to remain exempt as aforesaid; D
- (v) However, such registrants would otherwise remain bound by the prohibitory and penal provisions of the Act and would further remain liable to give inspection of the “silent observer” or other such equipment and their places, from time to time and in such manner as may be prescribed by the Central Supervisory Board; and E
- (vi) Rule 3(3)(1)(b) of the PNDDT Rules (as it stands after the amendment with effect from 9th January, 2014) is *ultra vires* the PNDDT Act to the extent it requires a person desirous of setting up a Genetic Clinic / Ultrasound Clinic / Imaging Centre to undergo six months training imparted in the manner prescribed in the Six Months Training Rules.” F

8. *Prima facie*, the High Court has erred in its finding that there is an absence of statutory power. Sub-section 1 of Section 32 of the PCPNDDT Act confers rule making power upon Central Government for “carrying out the provisions of the Act”. Illustratively, sub Section 2 of Section 32 stipulates that the rules may provide for: G

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A “(i) the minimum qualifications for persons employed at a registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under clause (1) of section 3.”

B The above provision refers to minimum qualifications required of persons employed at registered genetic counselling centres, genetic laboratories or genetic clinics under Section 3(2). Hence, it would be necessary to understand the import of Section 3 which reads thus:

“3. Regulation of Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics.-

C On and from the commencement of this Act,—

(1) no Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic unless registered under this Act, shall conduct or associate with, or help in, conducting activities relating to pre-natal diagnostic techniques;

D (2) no Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall employ or cause to be employed any person who does not possess the prescribed qualifications;

E (3) no medical geneticist, gynaecologist, paediatrician, registered medical practitioner or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person, any pre-natal diagnostic techniques at a place other than a place registered under this Act.”

F The expression ‘genetic counselling centre’ has been defined in Section 2(c) as follows:

“(c) “Genetic Counselling Centre” means an institute, hospital, nursing home or any place, by whatever name called, which provides for genetic counselling to patients”

G The expression ‘genetic laboratory’ is defined in Section 2(e) as follows:

(e) “Genetic Laboratory” means a laboratory and includes a place where facilities are provided for conducting analysis or tests of samples received from Genetic Clinic for pre-natal diagnostic test”

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The expression 'genetic clinic' is defined in Section 2(d) as follows: A

“(d) “Genetic Clinic” means a clinic, institute, hospital, nursing home or any place, by whatever name called, which is used for conducting pre-natal diagnostic procedures”

Under Section 2(d), 'genetic clinic' is defined with reference to the place which is used for conducting pre-natal diagnostic procedures. 'Genetic laboratory' in Section 2(e) includes a place where facilities are provided for conducting analysis or tests of samples received from a genetic clinic for a pre-natal diagnostic test. B

The expression 'pre-natal diagnostic procedures' is defined in Section 2(i) as follows: C

“(i) “pre-natal diagnostic procedures” means all gynaecological or obstetrical or medical procedures such as ultrasonography foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, blood or any tissue of a pregnant woman for being sent to a Genetic Laboratory or Genetic Clinic for conducting pre-natal diagnostic test” D

Both Sections 2(i) and Section 2(k) contain a specific reference to ultrasonography. The expression 'sonologist or imaging specialist' is defined in Section 2(p) as follows: E

“(p) sonologist or imaging specialist” means a person who possesses any one of the medical qualifications recognised under the Indian Medical Council Act, 1956 (105 of 1956) or who possesses a post-graduate qualification in ultrasonography or imaging techniques or radiology” F

Section 4 provides thus:

“4. Regulation of pre-natal diagnostic techniques. - On and from the commencement of this Act,—

(1) no place including a registered Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall be used or caused to be used by any person for conducting pre-natal diagnostic techniques except for the purposes specified in clause (2) and after satisfying any of the conditions specified in clause (3); G

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- A (2) no pre-natal diagnostic techniques shall be conducted except for the purposes of detection of any of the following abnormalities, namely:—
- (i) chromosomal abnormalities;
 - (ii) genetic metabolic diseases;
- B (iii) haemoglobinopathies;
- (iv) sex-linked genetic diseases;
 - (v) congenital anomalies;
 - (vi) any other abnormalities or diseases as may be specified by the Central Supervisory Board;
- C [(3) no pre-natal diagnostic techniques shall be used or conducted unless the person qualified to do so is satisfied that any of the following conditions are fulfilled, namely:—
- (i) age of the pregnant woman is above thirty-five years;
 - (ii) the pregnant woman has undergone two or more spontaneous abortions or foetal loss;
- D (iii) the pregnant woman had been exposed to potentially teratogenic agents such as drugs, radiation, infection or chemicals;
- (iv) the pregnant woman or her spouse has a family history of mental retardation or physical deformities such as, spasticity or any other genetic disease;
- E (v) any other condition as may be specified by the Central Supervisory Board;
- F Provided that the person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic in such manner, as may be prescribed, and any deficiency or inaccuracy found therein shall amount to contravention of the provisions of section 5 or section 6 unless contrary is proved by the person conducting such ultrasonography;
- G (4) no person including a relative or husband of the pregnant woman shall seek or encourage the conduct of any pre-natal diagnostic techniques on her except for the purpose specified in clause (2).
- H (5) no person including a relative or husband of a woman shall seek or encourage the conduct of any sex-selection technique on her or him or both.]”

Section 4(2) specifies exceptional situations in which a pre-natal diagnostic test may be conducted to detect certain specified abnormalities. Section 4(3) provides that no pre-natal diagnostic test shall be used or conducted unless the person qualified to do so, is satisfied for reasons to be recorded in writing that specific conditions (which have been laid down) are fulfilled. Section 5(2) contains a prohibition on the disclosure to a pregnant woman or to a relative of the sex of the foetus. Section 6 contains a prohibition on the determination of sex and on sex selection.

9. *Prima facie*, these provisions indicate that Parliament has conferred upon the Central government rule making authority to specify minimum qualification for persons to be employed at genetic counselling centres, laboratories and clinics. Specification of qualifications, in our view, should be read in a purposive sense which will fulfil the object of the law. Even on a plain and natural construction of the words used by Parliament, specification of qualifications must necessarily comprehend the power to prescribe training. The rationale for this is that the training would sensitize the person concerned to the salutary object and purpose of the legislation which has been enacted by Parliament to deal with a serious social evil and be conscious of the misuse of sex-selection tests. Pre-natal diagnostic procedures are susceptible to grave misuse.

10. Parliament which has the unquestioned authority and legislative competence to frame the law considered it necessary to empower the Central government to frame rules to govern the qualifications of persons employed in genetic counselling centres, laboratories and clinics. The wisdom of the legislature in adopting the policy cannot be substituted by the court in the exercise of the power of judicial review. *Prima facie* the judgment of the Delhi High Court has trespassed upon an area of legislative policy. Judicial review cannot extend to reappreciating the efficacy of a legislative policy adopted in a law which has been enacted by the competent legislature. Both the Indian Medical Council Act, 1956 and the PCPNDT Act are enacted by Parliament. Parliament has the legislative competence to do so. The Training Rules 2014 were made by the Central Government in exercise of the power conferred by Parliament. *Prima facie*, the rules are neither *ultra vires* the parent legislation nor do they suffer from manifest arbitrariness.

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A 11. For the reasons that we have indicated, we are of the view that the judgment of the Delhi High Court needs to be stayed during the pendency of these proceedings. The judgment of the High Court squarely impinges upon the directions issued by this Court in **Voluntary Health Association of Punjab**. We direct in consequence that the judgment of this Court in **Voluntary Health Association of Punjab** shall be strictly enforced by all states and union territories untrammelled by any order of any High Court or any other court.

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12. Pending final disposal, there shall be a stay of the operation of the judgment and order of the Delhi High Court dated 17 February 2016. The interlocutory applications are disposed of accordingly.

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Kalpana K. Tripathy

IAs disposed of.