* IN THE HIGH COURT OF DELHI AT NEW DELHI

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Date of decision: 17th February, 2016

+ <u>W.P.(C) 6968/2011</u>

INDIAN RADIOLOGICAL AND IMAGING ASSOCIATION (IRIA) Petitioner Through: Mr. Prateek Dahiya, Adv.

Versus

UNION OF INDIA AND ANR Respondents Through: Mr. Sanjay Jain, ASG with Mr. Jasmeet Singh, CGSC, Ms. Kritika, Mr. Vidur Mohan, Ms. Shreya Sinha & Mr. Srivats, Advs. for UOI. Mr. T. Singhdev and Mr. Vishu Agarwal, Advs. for MCI.

AND

+ <u>W.P.(C) 2721/2014</u>

INDIAN MEDICAL ASSOCIATION Petitioner

Through: Mr. Jayant Bhushan, Sr. Adv. with Mr. Netesh Jain, Adv.

Versus

UNION OF INDIA

..... Respondent

Through: Mr. Sanjay Jain, ASG with Mr. Jasmeet Singh, CGSC, Ms. Kritika, Mr. Vidur Mohan, Ms. Shreya Sinha & Mr. Srivats, Advs. for UOI. Mr. T. Singhdev and Mr. Vishu Agarwal, Advs. for MCI.

AND

+ <u>W.P.(C) 3184/2014</u>

SONOLOGICAL SOCIETY OF INDIA

Through: Petitioner-in-person.

Versus

UNION OF INDIA & ANR. Through: Mr. Sanjay Jain, ASG with Mr. Jasmeet Singh, CGSC, Ms. Kritika, Mr. Vidur Mohan, Ms. Shreya Sinha & Mr. Srivats, Advs. for UOI. Mr. T. Singhdev and Mr. Vishu Agarwal, Advs. for MCI. RAM:

CORAM: HON'BLE THE CHIEF JUSTICE HON'BLE MR. JUSTICE RAJIV SAHAI ENDLAW

RAJIV SAHAI ENDLAW, J.

<u>W.P.(C) No.6968/2011</u>.

1. The petitioner claims to be a Society registered under the Societies Registration Act, 1860 established with the aim and objective *inter alia* to promote the study and practice of radio-diagnosis, ultrasound, CT, MRI and other imaging modalities and, having more than 8600 radiologists and imaging experts having recognised post-graduate degrees in the field of radio-diagnosis and imaging recognised by the Medical Council of India (MCI) as its members. The petition is filed contending:

W.P.(C) Nos.6968/2011, 2721/2014 & 3184/2014

..... Petitioner

(i) that to overcome the growing problem of sex-selective termination of pregnancy of female foetuses after determining sex of the foetus by using pre-natal sex determination techniques, the Preconception and Pre-natal Diagnostic Techniques (Prohibition of Sect Selection) Act, 1994 (PNDT Act) was enacted with the objective of prohibition of sex selection and for regulation of misuse of pre-natal diagnostic techniques and the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996 (PNDT Rules) framed thereunder for matters connected therewith;

(ii) that though the aim of the Act was to restrict the use of ultrasound machine by allowing use thereof only by qualified individuals, who could be monitored, the same has had the opposite effect of enlarging the category of persons authorised to use and operate ultrasound machines;

(iii) that the PNDT Act, owing to its lackadaisical and ineffective implementation, has failed to serve the purpose and the child sex ratio continues to fall;

that this lead to the filing of W.P.(C) No.301/2000 titled Centre (iv) for Enquiry Into Health and Allied Themes (CEHAT) Vs. Union of India in the Supreme Court of India and vide order dated 4th May, 2001 wherein, directions were issued (i) to the Central Government to create public awareness against the practice of pre-natal determination of sex and female foeticide through appropriate releases / programmes in the electronic media; (ii) to implement with all vigour and zeal the PNDT Act and PNDT Rules and to strictly adhere to the rule as to the periodicity of meetings of the Advisory Committees constituted under Section 17(5) of the PNDT Act; (iii) to the Central Supervisory Board constituted under the Act to review and monitor the implementation of the Act and to seek quarterly returns from the States / Union Territories and to make recommendations as may be required as per the exigencies of the situation; and, (iv) to the Appropriate Authorities under the Act to take prompt action with respect to violators of the Act;

- (v) that the aforesaid directions of the Supreme Court also did not serve the purpose, as was lamented by the Supreme Court in the subsequent order dated 10th September, 2003 in the aforesaid petition;
- (vi) that the aforesaid resulted in amendment to the Act and the Rules being mooted and certain amendments were carried out to the Act with effect from 14th February, 2003;
- (vii) that Section 2(p) of the amended PNDT Act defines a "sonologist or imaging specialist" as:

(p) sonologist or imaging specialist" means a person who possesses any one of the medical qualifications recognised under the Indian Medical Council Act, 1956 (102 of 1956) or who possesses a post-graduate qualification in ultrasonography or imaging techniques or radiology.

but there is no post-graduate qualification, neither in the field of ultrasonography nor in the field of imaging techniques which is recognised by the respondent No.2 MCI;

(viii) that similarly the amended Rule 3(3)(1) of the PNDT Rules entitles the following persons to set up a genetic clinic / ultrasound clinic / imaging centre 3.3.(1) Any person having adequate space and being or employing—

(a) Gynaecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc. under supervision of an experienced gynaecologist in these fields, or

(b) a Sonologist, Imaging Specialist, Radiologist or Registered Medical Practitioner having Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning; or

(c) a medical geneticist,

may set up a genetic clinic/ultrasound clinic/imaging centre.

but there is no qualification recognised by MCI in the field of sonography or image scanning and the same enables registered medical practitioners, who as per MCI are not qualified, to set up the sonographic clinic or an imaging centre;

(ix) that representations to the aforesaid effect were made to the Central Supervisory Board constituted under the Act which though had been deliberating thereon, had failed to take any decision;

(x) that though the Rules aforesaid also speak of a six months training in sonography or image scanning but no formal training

programme has been devised;

(xi) that the PNDT Act is not concerned with conferring or recognising medical qualifications, the sole repository whereof is the respondent No.2 MCI.

- 2. The petition seeks a declaration:
 - that Section 2(p) of the PNDT Act to the extent it (a) recognises a person possessing a post-graduate qualification in ultrasonography or imaging techniques inasmuch bad as there is no post-graduate as qualification in ultrasonography or imaging techniques recognised by the MCI;
 - that Rule 3(3)(1)(b) of the PNDT Rules to the extent it (b) permits sonologists, imaging specialists or registered medical practitioner having six months training or one year experience in sonography or image scanning to set ultrasound clinics or imaging centres, is up unconstitutional, is qualification as there no in sonography and image scanning recognised under the Indian Medical Council Act, 1956 (MCI Act).

We may notice that though averments in the petition are also made with respect to the appointments under Section 17 of the Act of District Magistrates / District Collectors as District Appropriate Authorities and of the meetings of the Central Supervisory Board constituted under the PNDT Act but at the time of hearing, no arguments were addressed in that behalf and we as such do not deem it appropriate to deal therewith.

3. The respondent No.1 Union of India (UOI) has filed a counter affidavit to this petition pleading (a) that though PNDT Act is a central legislation committed to providing a legal framework for intensifying efforts to curb the practice of sex determination but the implementation of the Act lies primarily with the States which are expected to enforce the said Act through the statutory bodies in the States constituted under the Act; (b) that the MCI Act recognises the medical qualification of Doctor of Medicine M.D. (Radio Diagnosis) which is registered as M.D. (Radio Diagnosis) / Diploma in Radio Diagnosis (DMRD); (c) imaging techniques and ultrasonography is a critical part of the discipline of M.D. (Radiology) / DMRD to equip a medical professional to practice, teach and do research in the broad discipline of radiology including ultrasound; (d) that the MCI has

submitted guidelines enumerating the minimum criteria regarding qualification, training, accreditation of training institutes, for determining who should be recognised as qualified to undertake ultrasound test and have valid registration under the PNDT Act; (e) that the Central Government is in the process of finalizing the requirements in terms of qualifications and training required to be registered as a sonologist and the same shall be explicated as amendment to Rule 3(3)(1)(b) of the PNDT Rules; (f) that the Central Supervisory Board had considered the representations and the suggestions and had not considered any amendment to Section 2(p) of the PNDT Act to be necessary and was of the opinion that the purpose could well be achieved by amending Rule 3(3)(1)(b) of the Rules; and, (g) that the Central Supervisory Board has decided that in view of shortage of doctors with post-graduate qualification on the one hand and the growing demand of ultrasound services on the other, amendment of Section 2(p) of the PNDT Act is unnecessary and the purpose could be served by amendment of Rule 3(3)(1)(b) by laying down the criteria with regard to educational qualification for eligibility for training, length and content of training, accreditation of training institutions as well as the experience.

4. in rejoinder The petitioner its has pleaded that though ultrasonography is a part of the curriculum in MD in Radiology but is not a separate discipline and is not so recognised by the MCI and Rule 3(3)(1)(b)is therefore admittedly illegal, inasmuch as there is no recognised discipline of medicine known as sonologist and there is no post-graduate qualification in ultrasonography or imaging techniques recognized by the MCI. It is further pleaded that the post-graduate training programme for MD in radio diagnosis and DMRD is not a post-graduate qualification, either in the field of ultrasonography or imaging techniques.

5. The respondent No.2 MCI failed to file any counter affidavit inspite of opportunity.

6. The disposal of the petition was delayed for the reason of the counsel for the Union of India (UOI) from time to time informing that a Transfer Petition has been filed before the Supreme Court and notice thereof had been issued. However, when inspite of waiting for sufficiently long time no order for transfer was received and on the contention of the petitioner that the matter before the Supreme Court was distinct, the hearing of the petition was begun. 7. During the pendency of the petition, the PNDT Rules were amended vide Notification dated 9th January, 2014.

W.P(C) No.2721/2014.

8. This petition is filed impugning the Notification dated 9^{th} January, 2014 amending Rule 3(3)(1)(b) of the PNDT Rules as well as the amended Rule. The amended Rule 3(3)(1)(b) is as under:-

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; (c)

- 9. It is the contention of the petitioner
 - (a) that the aforesaid Rule is contrary to the PNDT Act as it contains an additional requirement of a six months training to be registered as a sonologist when the Act does not contain such an additional requirement and enables an MBBS doctor to be registered as a sonologist; the Rule is thus beyond the Act;

- (b) that Rule 6 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training), Rules, 2014 (Six Months Training Rules) also notified vide the same Notification dated 9th January, 2014 is as under:-
 - 6. Eligibility for training.-(1)Any registered medical practitioner shall be eligible for undertaking the said six months training.
 - (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 month 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.

It is argued that thus the said Rule not only prescribes six

months training to register as a sonologist but even requires existing sonologist to qualify a competency based assessment to renew the registration and consequently provides that if the existing sonologist fails to clear the said assessment, he would be required to undertake the complete six months training. It is contended that the Rule is unreasonable and illogical – the curriculum for graduation of MBBS doctors includes specific knowledge and skills in the field of radio-diagnosis and imaging and the knowledge and skills set out in the Six Months Rules is merely a repetition of the knowledge and skills set out in the curriculum of MBBS doctors. It is argued that it is unreasonable and illogical for an MBBS doctor to undergo additional six months training under the Six Months Training Rules for the same knowledge and skills that he has already gained in his curriculum;

- (c) that though as per PNDT Act, MBBS doctors are sonologist but the Authorities under the said Act do not register the MBBS doctors as sonologist compelling them to take additional six months training or one year experience and which is not required by the Act; and,
- (d) that now-a-days ultrasound is not being treated as a specialty but as a diagnostic tool like stethoscope and many institutions are running courses for non-medical persons to do echocardiography etc.

- 10. It is the stand of the respondent UOI in its counter affidavit
 - (i) That the impugned Notification dated 9th January, 2014 was preceded by a consultative process pursuant to the judgment dated 5th July, 2010 of a Single Judge of this Court in W.P.(C) No.6654/2007 titled *Dr. K.L. Sehgal Vs. Office of District Appropriate Authority* highlighting the need for prescribing qualifications of a person seeking to run diagnostic clinics and for prescribing the qualification, training and experience to be recognised and registered as a sonologist.
 - (ii) That to the said consultative process MCI was also privy and proposed a framework of minimum criteria regarding qualification, training, accreditation of training institutions and the contents of the training. The framework proposed by MCI was re-evaluated by a broad based Core Committee and which in turn appointed an Expert Committee. The recommendations of the Expert Committee and the Core Committee were considered by the Central Supervisor Board constituted under the PNDT Act and only thereafter the amendment to Rule 3(3)(1)(b) and the Six Months Training Rules were notified.

- (iii) That neither Rule 3(3)(1)(b) as amended vide Notification dated 9th January, 2014 nor the Six Months Training Rules contravene any provision of the PNDT Act.
- (iv) That the Secretary General of the petitioner is also a notified member of the Central Supervisory Board but the petitioner has not acted proactively in the matter.
- (v) That the Six Months Training Rules would ensure better quality among all member of profession by making the six months training mandatory and uniform throughout the country for the registered medical practitioners.
- (vi) That registered medical practitioners possessing any of the medical qualification as prescribed in Section 2(h) of the MCI Act may set up a genetic clinic / ultrasound clinic / imaging centre based on their MCI recognised qualification and subsequent mandatory six months training in sonology as prescribed in Six Months Training Rules.
- (vii) That though Rule 3(3)(1)(b) supra prior to its amendment w.e.f.
 9th January, 2014 also mentioned six months training but did not specify the nature and duration of six months training,

necessitating amendment thereof.

- (viii) That the amendment aforesaid also became necessary in view of the observations of this Court in *K.L. Sehgal* supra and has been effected after a detailed consultative process.
- (ix) That the amended Rule 3(3)(1)(b) is within the rule making power of the Central Government under Section 32 of the PNDT Act and the Notification dated 9th January,2014 was duly laid on the Table of both the Houses of Parliament.
- (x) Rule 6(2) of the Six Months Training Rules exempts those registered medical practitioners from undertaking the six months training who are having experience of one year or more in ultrasonography and who had already undergone six months training, provided they pass the prescribed competency based assessment. To conduct such competence based test for registered medical practitioners having one year experience or six months training, the States have been given time till 1st January, 2017, by which time the States are expected to complete the assessment and fulfil the training requirements of the registered medical practitioners.

- (xi) The Six Months Training Rules came into force w.e.f. 9th January, 2014 in case of new registrations only; however earlier registrants will have to either undergo training or if claim exemption will have to qualify the competency based test on or before 1st January, 2017. Liberty has thus been provided for all registrants prior to 9th January, 2014 and the amended Rule 3(3)(1)(b) and the Six Months Training Rules are thus not illogical or arbitrary.
- (xii) The knowledge and skill set out in the Six Months Training Rules are not a repetition of the knowledge and skills set out in the graduate medical curriculum for MBBS doctors. The syllabus set out for the MBBS doctors is quite general in nature, while the curriculum as prescribed in the Six Months Training Rules is specific and known as "Fundamentals In Abdomino Pelvic Ultrasonography: Level-one 6 Months Course for MBBS doctors". The radiology curriculum for MBBS doctors is mostly theoretical, providing for only 30 hours of clinical posting in radiology. On the other hand the curriculum prescribed in the Six Months Training Rules

contains theory as well as practical training of 300 hours duration. Further, MBBS curriculum clubs the doctors in terms of central development, only to devise appropriate diagnostic procedures in specified circumstances but not proficient in conducting such diagnostic procedures. On the contrary the curriculum under the Six Months Training Rules enables the registered medical practitioners to be proficient in conducting the ultrasonography as a diagnostic tool.

- (xiii) The training will equip the registered medical practitioners professionally and would also sensitise them to the declining trend of child sex ratio and their responsibility towards it as an important stakeholder; and,
- (xiv) Easy access to ultrasound diagnostic techniques since the early
 1980s has contributed to the increased opportunity of sex
 selection with increased incidences of female foeticide
 resulting in the rapid decline in the child sex ratio.

<u>W.P.(C) No.3184/2014.</u>

11. This petition is filed by a society established with the aim and objective to promote awareness in the field of diagnostic ultrasound and to

educate and spread awareness amongst general public against female foeticide, and with medical professionals as its members.

12. The cause of action for the said petition is the Circular dated 27th March, 2014 of the respondent No.2 Directorate of Family Welfare, Govt. of NCT of Delhi (GNCTD) and on the basis whereof it is averred that registration / renewal of registration is not being granted to several members of the petitioner running ultrasound clinics.

13. It is the contention of the petitioner, (i) that though this court in *K.L. Sehgal* supra clarified that as long as the person concerned possesses one of the medical qualifications recognised under the MCI Act, he could be a sonologist and that the word "or" between the words "...Indian Medical Council Act, 1956 (102 of 1956)" and "who possess a post-graduate qualification..." in Section 2(p) of the PNDT Act is not to be read as "and", the respondents are insisting upon persons holding medical qualification recognised by the MCI also either underging a six months training or passing a competency test; (ii) that Rule 3(3)(1)(b) as amended with effect from 9th January, 2014 is contrary to Section 2(p) of the Act as interpreted by this Court in *K.L. Seghal* supra; (iii) that various members of the

petitioner society who are registered medical practitioners in terms of Section 2(m) of the PNDT Act and are sonologist in terms of the definition in Section 2(p) of the Act as interpreted by this Court in K.L. Sehgal, are not being granted registration / renewal of registration of their ultrasound clinics citing the amendments dated 9th January,2014 to the PNDT Rules and the Circular dated 27th March, 2014 supra; (iv) that the amendment to Rule 3(3)(1)(b) of the PNDT Rules is thus in violation of the judgment of this Court in K.L. Sehgal supra; (v) that denial of registration / renewal of registration under the PNDT Act to the medical practitioners who are sonologist in terms of Section 2(p) of the Act is in restraint of their fundamental right to carry on lawful trade; (vi) that the amendment of Rule 3(3)(1)(b) has retrospective application inasmuch as, even those MBBS doctors who are sonologist in terms of Section 2(p) of the PNDT Act and have been practising ultrasound since decades and have international recognition in the field of ultrasound have to appear in competency test, while all the post-graduates have been exempted, even though many of them have no exposure to ultrasound at any stage; (vii) that the amended Rule 3(3)(1)(b) is discriminatory and violative of Article 14 of the Constitution of India as all the post-graduates have been exempted from undertaking six

months training, even though many of the Post Graduate (PG) speciality courses vis. physiology, microbiology, biochemistry, pathology etc. do not have ultrasound training in the curriculum; (viii) that though in terms of the amended Rule 3(3)(1)(b), all registered medical practitioners having PG degrees / diplomas in any speciality can open and run ultrasound clinic and get registered under the PNDT Act, but as per the Circular dated 27th March, 2014 only post-graduate degree / diploma holders in obstetrics, gynaecology radiology will be entitled for registration under the PNDT Act; (ix) that ultrasound is a modality like modern day stethoscope; (x) that no other modality training like ECG, laparoscope etc. require PG Entrance Exam; (xi) that in India the doctor-patient ratio is very poor; in many places sonologist patient ratio is one for a population of five lakhs; (xii) that the impugned notification will further lead to shortage of sonologist and which will not be in the interest of the patients; and, (xiii) that in terms of the judgment of this Court in K.L. Sehgal supra, the change would only be prospective and not retrospective.

14. The petition (I) seeks a mandamus to the Union of India and Directorate of Family Welfare of GNCTD to grant registration / renewal of registration under the PNDT Act to those medical practitioners who come

under the realm of definition of sonologist in terms of Section 2(p) of the PNDT Act; and, (II) seeks quashing of the amendment dated 9th January, 2014 to Rule 3(3)(1)(b) of the PNDT Rules and notifying the Six Months Training Rules to the extent inconsistent with the definition of sonologist under Section 2(p) of the PNDT Act.

UOI filed its counter affidavit dated 22nd September, 2014 to this 15. petition pleading (a) that the child sex ratio has been continuously declining all over India including in the rural and far flung areas; the child sex ratio presently is the lowest since independence; (b) that to overcome the malady of termination of pregnancy after determining the sex of the foetus by using pre-natal techniques, the PNDT Act and PNDT Rules were enacted; (c) that though Rule 3(3)(1)(b) as it stood prior to its amendment with effect from 9th January, 2014 mentioned six months training and one year experience but the institutions / individuals from which /whom this experience / training was to be obtained were not specified; (d) that this resulted in numerous ultrasonographic centres flourishing across the country making ultrasonography tests without standardised training / curriculum and resulting in mushrooming ultrasonographic centres by ill-qualified/poorly trained sonologist resulting in unethical practises throughout the country;

(e) observations to this effect were made by this Court in *K.L. Sehgal*; (f) that in compliance with the observations in *K.L. Sehgal*, the PNDT Rules were amended and the Six Months Training Rules notified with effect from 9^{th} January, 2014; (g) denying that there is any retrospectivity in the amendment with effect from 9^{th} January, 2014; (h) denying that there is any discrimination in exempting the registered medical practitioners having post-graduate degree / diploma in radiology / imaging or sonography from the six months training; it is stated that all those having PG degree / diploma in obstetrics, gynaecology are also exempted from the said training; (i) that the amendments with effect from 9^{th} January, 2014 apply only for new registration; however old sonologist have been given time to pass the competency test on or before 1^{st} January, 2017.

16. The respondent No.2 Directorate of Family Welfare, GNCTD in its counter affidavit has pleaded that by virtue of the amendment with effect from 9th January, 2014, doctors possessing MBBS degree who were practising as sonologist by claiming to have six months training or having one year experience from any unregulated hospital / training institute / individual doctor, would henceforth be required to satisfy the requirements of Rules 6 & 7 of the Six Months Training Rules *inter alia* by undergoing a

prescribed 300 clock hours curriculum course to be spread over six months to be conducted by identified accredited institutions recognised either by the MCI or the National Board of Medical Speciality or centres of excellence established by an Act passed by the Parliament; however those who are qualified as PG in radiology and gynaecology/obstetrics will continue to be eligible for registration as they are exempted from training.

CONTENTIONS.

17. The counsel for the petitioner in W.P.(C) No.6968/2011 argued (i) that there is no post-graduate qualification in ultrasonography or imaging techniques or radiology as mentioned in Section 2(p) of the Act; (ii) that there is no qualification as a sonologist or imaging specialist as mentioned in Rule 3(3)(1)(b); (iii) support in this regard was drawn from the reply dated 1st June, 2011 of the MCI to a query under the Right to Information Act, 2005, to the effect that MCI does not recognise certificate course issued by the radiologist for ultrasonography training.

18. The senior counsel for the petitioner in W.P.(C) No.2721/2014 contended (i) that prior to coming into force of the PNDT Act, even a person having a decree of MBBS, not necessarily of M.D. (Radiology) could own and operate a ultrasound machine; (ii) that Section 2(p) of the

Act also includes in the definition of sonologist or imaging specialist, every such person who holds a medical qualification recognised by the MCI, again recognising persons holding the MBBS qualification as sonologist and imaging specialist; (iii) that there is no post-graduate qualification in ultrasonography or in imaging techniques; (iv) that under Section 32 of the Act the power of the Central Government to make Rules extends only to make rules for minimum qualifications of persons employed at the registered genetic counselling centre, genetic laboratory or genetic clinic and not to make rules for persons employed at ultrasound clinics; (v) that the technique of ultrasound is used for diagnostic purpose qua various organs and not only for sex determination and thus all clinics using ultrasound machines would not qualify as genetic clinics; (vi) instance is given of specialist hospitals / clinics dealing with specific organs, say heart, lung or liver and it was contended that they also use ultrasound machine but can by no stretch of imagination be called a genetic clinic; (vii) that the requirement, in Rule 3(3)(1)(b) as amended with effect from 9th January, 2014, of six months training can only be qua registered medical practitioners as defined in Rule 2(ee) of the Drugs and Cosmetics Rules, 1945 and cannot possibly be qua those who qualify as sonologist within the

meaning of Section 2(p) of the Act; (viii) alternatively, Rule 3(3)(1)(b) has to be confined to the genetic clinics only and cannot be extended to ultrasound clinics; all ultrasound clinics are not genetic clinics; those who have been practising as a radiologist or have been using ultrasound for tens of years cannot be asked to undergo six months training or take any test, as the same cannot take the place of their experience of decades; (ix) that the amendment of Rule 3(3)(1)(b) w.e.f. 9th January, 2014 takes away the one year experience in sonography or image scanning as existed earlier and thus Rule 6(2) of the Six Months Training Rules is bad; and, (x) that under Rule 8 there was/is a right of renewal of registration; the amendment w.e.f. 9th January, 2014 takes away the said right; reliance is placed on G.P. Singh's Interpretation of Statues to urge that interpretation rendering certain words otiose, cannot be adopted and on Dr. Indramani Pyarelal Gupta Vs. W.R. Nathu AIR 1963 SC 274 laying down that the Central Government as a delegate of the legislature, without being specifically empowered can only make Rules having prospective operation and not with retrospective effect.

19. At this stage, the counsel for the petitioner in W.P.(C) No.6968/2011 contended that PNDT Act was concerned with the misuse of the techniques of ultrasound for sex determination but has ended up, permitting all MBBS Doctors to conduct ultrasound. However on enquiry, whether prior thereto, there was any bar on MBBS Doctors doing ultrasound or reporting on ultra sound procedure, no reply was forthcoming.

20. The office bearer of the petitioner in W.P.(C) No.3184/2014 arguing in person addressed the same arguments, as the senior counsel for the petitioner in W.P.(C) No.2721/2014 and contended that all MBBS Doctors, without any post-graduate qualification in radiology, are in any case entitled to conduct ultrasound and if it were to be held that only those with postgraduate qualification in radiology can conduct ultrasound, the same would require frequent referrals to such specialist and increase in the cost of treatment.

21. The senior counsel for the petitioner in W.P.(C) No.2721/2014 resuming his arguments contended that the provisions of six months training for a person holding qualification recognised by the MCI is otiose. Reliance in this regard was placed on *Academy of Nutrition Improvement Vs. Union of India* (2011) 8 SCC 274. It was contended that the issue of misuse of

technology for sex determination is a moral one and has nothing to do with training. It was further contended that since the Act is intended to prevent sex determination, it cannot possibly apply to a Heart Institute. We were informed that owing to the respondents interpreting the term genetic clinic as meaning all places where ultrasound machines are kept, reputed and wellknow medical professions also having an ultrasound machine or even a portable equipment in their clinic though intended for use in their respective specialisations but capable of determining sex are forced to get themselves registered as a genetic clinic and to comply with the provisions of the Act and the Rules and which is not only cumbersome but also leaves their patients nonplussed on seeing the proclamations in their clinic in compliance of the Act and the Rules as if it is a genetic clinic. We were informed that owing thereto several doctors are opting not to keep a ultrasound machine or other such alternate portable equipment in their clinics, much to their handicap and to the inconvenience of their patients.

22. The learned ASG defending the challenge argued (i) that the fountainhead for the amendments of the year 2014 to the Rules is the judgment of this Court in *K.L. Sehgal's* case; ii) attention was invited to Section 16 of the Act prescribing the functions of the Central Supervisory

Board constituted under the Act and the minutes of the meetings of the Board leading to the amendment; iii) the amendments of the year 2014 do not become retrospective by requiring those practising ultrasonography to either take the competency test or undergo six months training; iv) attention was drawn to Statement of Objections & Reasons of the PNDT Act; v) that as per the Act, any person can open a genetic clinic, provided a qualified person is employed therein; vi) that the explanation to Section 2(d) of the Act applies to a place other than vehicle also; vii) that the challenge in all the petitions is to the six months training and none should have any objection to obtaining an added qualification; viii) that the wisdom of the policy is not to be gone into by the court; (ix) that the un-amended Rule 3(3)(1)(b) also provided for training though none was prescribed and the amendment is intended to end un-channelised system of training of sonologist; and, (x) better training will raise standards.

23. The written submissions filed have also been perused.

DISCUSSION.

24. We had during the hearing enquired from the counsels whether it is technically possible to fit/load ultrasound machine with a device/programme disabling the use thereof for sex determination or for scanning uterus.

25. We were however told that the same is not possible.

26. We had further enquired whether the respondents are open to taking a declaration, from medical practitioners though desirous of or in need of using an ultrasound machine, portable or otherwise, for purposes other than sex determination, to the effect that the same will not be used for scanning uterus or otherwise for sex determination and to exempt such practitioners from the provisions of the Act/Rules relating to training/competency test/ maintenance of records etc, though otherwise remaining liable for surprise inspections/raids etc and penalties for violations of the Act.

27. However no such concession was forthcoming from the side of the Government; rather the learned ASG suggested that the subject is a sensitive one which is seized of by the Supreme Court.

28. We have considered the controversy in totality.

29. We must say, we have been left wondering, what, the questions as have been raised before us, have to do with prevention of misuse of prenatal diagnostic techniques for sex determination, which was/is the only purpose / objective of the enactment of PNDT Act. For meeting the said objective/purpose, we fail to understand what difference it makes, whether the sonologist or imaging specialist i.e. a person who can use and operate an *W.P.(C) Nos.6968/2011, 2721/2014 & 3184/2014 Page 30 of 83*

ultrasound machine, is a mere MBBS or has a Post Graduate qualification in medicine or has experience of one year or has undergone six months training. The PNDT Act does not owe its enactment to the poor or useless or inaccurate diagnostic reports of ultrasound tests and resultant need to prescribe the qualifications of persons who can operate, use, read and report the outcome of the said diagnostic procedure. If it was felt that for practising medicine with the aid of an ultrasound machine, none of the medical qualifications contained in the Schedule to the MCI Act are sufficient or that only those with one or more of the said qualifications are competent to so practise, the MCI Act was/is in existence to serve the said purpose and there was no need for a new enactment to serve the said purpose. The PNDT Act owes its existence solely to the falling ratio of female child as against the male child and the cause whereof was found to be misuse of pre-natal diagnostic techniques for sex determination, in turn leading to female foeticide.

30. A perusal of the Statement of Objects & Reasons of the PNDT Act indeed shows that it was intended to prohibit pre-natal diagnostic techniques for determination of sex of foetus leading to female foeticide and to prevent abuse of techniques discriminatory against female sex and affecting dignity and status of women, by regulating the use of such techniques and to provide deterrent punishment to stop such inhuman act. The enactment was to achieve the objectives of:

- (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;
- (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.

The preamble of the Act is as under:

An Act to provide for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purposes of detecting genetic abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex-linked disorders and for the prevention of their misuse for sex determination leading to female foeticide and for matters connected therewith or incidental thereto.

31. An overview of the PNDT Act also shows all provisions thereof to be to serve the purpose/objective only of preventing misuse of pre-natal diagnostic techniques for sex determination. The PNDT Act is found by us to have been enacted (i) to prohibit/make sex determination and sex selection an offence; (ii) to prohibit sale of ultrasound and other machines capable of sex selection save to persons registered under the Act; (iii) to prohibit conduct/use of pre-natal diagnostic techniques except for detection of prescribed abnormalities and to prescribe the conditions (including maintenance of records) subject to which the prenatal diagnostic techniques shall be used for such limited purpose; (iv) to constitute Central Supervisor and State Supervisory Boards to advise the Central Government on policy matters relating to use of pre-diagnostic techniques and against their misuse, to monitor implementation of the Act and recommend changes in the Act and the Rules, to create public awareness, to lay down code of conduct to be observed in places where ultrasound machines are kept etc.; (v) to constitute Appropriate Authorities to grant registration under the Act and to enforce the provisions of the Act. Though Section 32 of the Act empowering the Central Government to make Rules for carrying out the provisions of the Act empowers the Central Government to make rules to provide for the minimum qualification for the persons employed at Genetic Counselling Centres, Genetic Laboratory or Genetic Clinic i.e. a place where ultrasound or like machine is kept but that in our opinion would only entitle the Central Government to provide that only persons holding any of the medical qualifications recognised by MCI, will be so employed (because

ultrasound and like machines are medical tools) but would not entitle the Central Government to prescribe or coin new or additional qualifications. We say so because that is not the provision in the Act and the Rules under Section 32 can be made only for carrying out the provisions of the Act. Once the PNDT Act is not found to be dealing with medical education, the power to make rule prescribing minimum qualification cannot be understood as a power to establish a qualification but has to be necessarily understood as power to prescribe only those qualifications which are recognised by MCI. This is more so since the Act in Section 2(m) and (p) expressly refers to qualifications recognized by MCI.

32. We are unable to find any provision in the PNDT Act empowering any of the bodies constituted thereunder i.e. the Central Supervisory Board or the State Supervisory Boards or the Appropriate Authorities or the Advisory Committees or even the Central Government to prescribe the qualifications for practising medicine with the aid of an ultrasound machine or to prescribe the nature and content i.e. curriculum of the said qualification or the duration of the qualification. The task of prescribing the education and training without which a person cannot practise in the field of medicine is a highly technical and important task requiring in depth knowledge of what all practise in that field of medicine entails as it is then only that the person before being permitted to practise therein can be equipped therewith. It is inconceivable that without any whisper even in any of the provisions of the Act in this regard, the Act could be intended to be or can be held to be concerned with prescribing the qualification and course content of that qualification for practising medicine with the aid of or through the medium of ultrasound machine. The said power cannot be generally inferred. In contradistinction, the MCI Act, enacted to provide for the reconstitution of the Medical Council of India and the maintenance of a Medical Register for India and for matters connected therewith, a) in sub Sections 10A, 10B, 11, 12, 13, 14 and 20 makes detailed provisions qua medical qualifications which are/can be recognised, b) vide Section 15, permits names of any those holding recognised medical qualifications to be entered in the Medical Register to be maintained and confers right in them only to practise medicine, c) vide Section 16 empowers the MCI to ensure that the medical colleges/institutions are imparting requisite medical education and holding examinations in the courses for which recognition has been given to them, d) vide Section 19 provides for withdrawal of recognition, e) vide Section 19A empowers MCI to prescribe minimum

standards of medical education, f) vide Section 20A empowers the MCI to prescribe the professional conduct, etiquette and code of ethics to be followed by medical practitioners, and so on. The Schedules to the MCI Act are found to give detailed description of recognised medical qualifications.

33. Not only so, even if the concern sought to be addressed by the PNDT Act were to be held to include use of ultrasound machines only by those who are educationally equipped and trained therefor, it belies logic, why the prescription in the Act in this regard would be confined to use of ultrasound machines only for pre-natal diagnostic procedures when it is undisputed that the said machines are used for other diagnostic procedures as well. There is not mention whatsoever thereof in the Act or the Rules (though interestingly mention thereof is made in the Six Months Training Rules). It cannot be that though the MCI recognised medical qualifications educate and train for use of ultrasound machine qua other diagnostic procedures but not qua prenatal. Certainly the legislature cannot be presumed to be so arbitrary as to, while addressing the concern of not allowing use of ultrasound machines by those who are not qualified therefor, address it qua one of the diagnostic procedures only and not others. It further cannot be presumed that though MCI is competent to prescribe and regulate award of medical qualifications
to enable a person to prescribe medicines and treatment to and even to conduct surgery on patients but not to do the same to enable a person to diagnose with the aid of ultrasound machine. In this regard it is also worth noting that under Section 10A of the MCI Act, the power of the Central Government to grant permission for establishment of medical colleges and for opening a new or higher course of study or training including a post graduate course of study or training, is "notwithstanding anything contained in this Act or any other law for the time being in force".

34. We are therefore unable to comprehend the purport of the impugned provisions prescribing the qualification of persons who can use and operate the ultrasound machines and like. It is not as if prior to the coming into force of the PNDT Act the ultrasound machines were in the hands of persons other than 'Doctors'. Even in diagnostic centres where 'technicians' were operating the ultrasound machines, they were under the control and supervision of 'Doctors' and it was the 'Doctors' who were preparing and signing the reports of ultrasound diagnosis/test. It was the 'Doctors' only who were misusing the same for sex determination, as is evident from reports in the news media of the stray cases detected of violation of the Act. 35. Section 16 of the PNDT Act prescribing the functions of the Central Supervisory Board constituted under Section 7 of the Act prescribes one of the functions as, to create public awareness against the practice of preconception sex selection and prenatal determination of sex of foetus leading to female foeticide. We find the Supreme Court also to have, in orders reported in (2001) 5 SCC 577, (2003) 8 SCC 398 and (2003) 8 SCC 410 in Centre For Enquiry into Health and Allied Themes (CEHAT) Vs. UOI as well as in orders reported in (2013) 4 SCC 1, (2014) 16 SCC 426 and (2015) 9 SCC 740 in Voluntary Health Association of Punjab Vs. UOI, repeatedly emphasised the need to sensitise the people and create public awareness against the practise of prenatal determination of sex and female foeticide.

36. Therefrom the legislative intent appears to be to allow use of ultrasound machines only by those who can be sensitised to the issue. Though to us it appears that the issue is a moralistic and not a legal one and such sensitisation is not dependent upon literacy and there appears to be no basis for presuming that the ultrasound machines prior to the coming into force of PNDT Act were in the hands of persons who could not even be so sensitised or for apprehension that they will be so in future, but we still fail

to see any nexus between the provisions of the PNDT Act and the aim and objective of enactment thereof on the one hand and the impugned PNDT Rule and the Six Months Training Rules with which we are concerned in these petitions, on the other hand

37. We are of the opinion that for the purposes of prevention of sex determination through ultrasound machines or other radiological techniques, it matters not whether the ultrasound machine is in the hands of an MBBS or an MBBS with six months training or an MBBS with one year experience who has cleared the competency test or in the hands of MD radiologist / obstetrics. The qualification of MBBS itself is a highly sought after qualification, to secure which one has to first appear in a competitive examination for admission to a medical college and thereafter has to undergo the rigours of passing the MBBS examination. By no stretch of imagination can it be said that an MBBS qualified person lacks education or understanding to be not able to comprehend the fatal consequence of female foeticide as a result of sex determination or the morality behind the same. In our opinion, to understand the said aspects, the one year experience or passing the competency test or undergoing the six months training or acquiring the post-graduate qualification, add no further to the person. To

make an as educated a person as a 'Doctor' understand the ill effects of sex determination and that use thereof for the purposes of female foeticide is a crime, there is no need to require him either to undergo post-graduation or a six months training or gain a one year experience or pass a competency test. By doing so, he will not be less likely to break the said law than he would be without the same. It is not as if holding a medical qualification recognised by MCI does not have any concern with the conduct/behaviour of the holder thereof. The holder thereof is required to abide by the standards of professional conduct and etiquette and code of ethics prescribed by MCI in exercise of power under Section 20A of the MCI Act. Moreover, when the holder of medical qualification is capable of being sensitised with the code of conduct/etiquette/ethics, he/she can certainly be sensitised to the issue of PNDT without being required to undergo any training/experience.

38. We are constrained to observe that in the matter of the said legislation, the destination appears to have been forgotten during the journey from September, 1991 when the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Bill, 1991 was first introduced in the Lok Sabha to the enactment of the PNDT Act and the Rules and the amendments thereto.

39. The result thereof is evident. Inspite of the law having been enacted nearly quarter of a century back, the child sex ratio continues to fall as admitted by the Union of India in its counter affidavit filed in the year 2014 in WP(C) No. 3184/2014. A surfing of the internet does not show any improvement thereafter either. The PNDT Act, clearly has failed to serve the purpose.

40. One of the reasons therefor, as far as we can gauge is the unnecessary emphasis on regulating and enforcing those provisions which do not serve the aim and objective of the Act and at the expense of detection of violations of the prohibitions imposed by the Act and which appear to continue unabated. The entire enforcement machinery created under the Act appears to be engrossed in the mammoth paper work of registration of ultrasound machines and other diagnostic tools, even if in use of medical professionals for non prenatal diagnosis and of ensuring that the records required to be maintained by the registrants are maintained. In all this exercise, there appears to be little time left for identifying those misusing the ultrasound machine for sex determination and who are going undetected. 41. We now proceed to deal with the rival contentions, to answer the following:

- A. Interpretation of Section 2(p) of the PNDT Act, i.e. who is authorised to operate and use a ultrasound machine.
- B. Whether Rule 3(3)(1)(b) of the PNDT Rules (after the amendment w.e.f.09.01.2014) is inconsistent with Section 2(p) of the PNDT Act and if so to what effect.
- C. Whether Rule 3(3)(1)(b) of the PNDT Rules (after the amendment w.e.f. 09.01.2014), to the extent it requires a person possessing one of the medical qualifications recognised by MCI Act to undergo six months training as prescribed in the Six Months Training Rules or if having experience of one year in ultrasonography, to take the competency test, for operating and using a ultrasound machine, is arbitrary and if so to what effect.

42. We may at the outset notice the difference in the stand qua the interpretation of Section 2(p) between the petitioner in WP(C) No. 6968/2011 and the petitioners in the other two petitions. While according to petitioner in WP(C) No. 6968/2011, which represents Doctors with postgraduate degrees in radio-diagnosis, it is only the Doctors with postgraduate degrees in radio-diagnosis who are competent to install, use, operate and report on diagnosis with ultrasound machines and have been doing so in the past and the PNDT Act has for the first time entitled even *W.P.(C) Nos.6968/2011, 2721/2014 & 3184/2014 Page 42 of 83*

those without postgraduate degrees i.e. mere MBBS to do so, the petitioners in other two petitions who represent the general body of Doctors, not necessarily holding postgraduate degree in radio-diagnosis, controvert. However since we have not been shown and have ourselves not been able to find any bar under the MCI Act or any other law/rule/regulation, to using/operating ultrasound machine save with a postgraduate degree in radio diagnosis, we proceed to interpret Section 2(p) literally.

43. Section 2(p) was subject matter of interpretation in *K.L. Sehgal* supra on which heavy reliance has been placed by the respondent Union of India in its counter affidavits as hereinabove recorded. It was the contention of the GNCTD in that case that the word "or" between the words "...Indian Medical Council Act, 1956 (102 of 1956)" and "who possess a postgraduate qualification..." in Section 2(p) of the PNDT Act has to be read as "and". This Court however rejected the said contention reasoning (a) that a plain reading of Section 2(p) shows that a person possessing one of the medical qualifications recognised under the MCI Act is a sonologist and the word "or" only makes possessing of the post-graduate qualification in ultrasonography or imaging techniques or radiology an alternative qualification; (b) that though prior to the insertion of Section 2(p) certain amendments

were proposed and in which instead of the word "or" the words "and / or" existed but in the ultimate enactment the word "and" was dropped meaning that the definition as was incorporated requires a post-graduate qualification only in the alternative; (c) that the understanding of the definition in Section 2(p) is also reflected in Regulation 3(3)(1)(b) (as it stood then i.e. prior to amendment w.e.f. 09.01.2014) which enabled a sonologist or a imaging specialist or a radiologist or registered medical practitioner having postgraduate decree or diploma or six months training or one year experience in sonography or image screening to set up a genetic clinic / ultrasound clinic / imaging centre; (d) that if the word "or" is read as "and", then the words which indicate that the person should be possessing one of the medical qualifications recognised under the MCI Act would be rendered redundant; (e) that to accept the argument that the word "or" should be read as "and" would be reading too many words into Section 2(p) of the PNDT Act, which is not simply permissible; (f) that MCI also in its letter dated 4th May, 2009 to one of the petitioners had intimated that a person who either has a MBBS degree or a further specialisation qualification would be able to run an ultrasound clinic provided he or she undergoes six months training in ultrasonography.

44. Union of India and GNCTD were parties to K.L. Sehgal and accepted the said judgment and allowed it to attain finality. They have now also not assailed the interpretation of Section 2(p) of PNDT Act therein. Rather, both in their respective counter affidavits have relied heavily thereon. The contention of the petitioners in WP(C)No. 2721/2014 and WP(C) No. 3184/2014 also is that qualification of MBBS or any medical qualification recognized under the MCI Act is enough to operate/use an ultrasound machine. It is only the petitioner in WP(C) No. 6968/2011 which contends that only those with postgraduate degree in radio-diagnosis can do so; however it has been unable to show any requirement of MCI in this regard. We have already hereinabove held that the aim and objective of the PNDT Act was not to prescribe the qualification of persons eligible / qualified to do medical diagnosis with the aid of ultrasound machine but to only prevent misuse thereof for sex determination resulting in female foeticide. We have not been told or are able to comprehend as to how, to serve the said purpose it is relevant whether the ultrasound machine is in hands of a person having qualification of MBBS or of a person holding qualification of M.D. (Radio-Diagnosis). If MCI, which is the specialist body in the field of medicine, is of the opinion that persons having MBBS qualification are entitled to

practise medicine with use of ultrasound machine, we need look no further. In this light of the matter we do not feel the need to consider the correctness of the interpretation of Section 2(p) in *K.L. Sehgal* supra. We also do not find the amendment of Rule 3(3)(1)(b) w.e.f. 09.01.2014 i.e. after *K.L. Sehgal*, to have any effect thereon. Suffice it is to state that literally, Section 2(p) enables a person who possesses any one of the medical qualification recognised by MCI to be a sonologist or imaging specialist.

45. We will next take up the question, whether the Rule 3(3)(1)(b) of the PNDT Rules as amended w.e.f. 09.01.2014 is contrary to the PNDT Act.

46. Rule 3(3)(1)(b) prescribes the qualifications of those who can set up or those who can be employed in a genetic clinic, ultrasound clinic or a imaging centre. The word employee is defined in Rule 2(b) as a person working in or employed by a genetic clinic or an ultrasound clinic or an imaging centre including those working on part-time, contractual, consultancy, honorary or on any other basis.

47. The Act defines genetic clinic and genetic laboratory in Section 2(d) and (e) thereof as under:

(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;

Explanation- For the purposes of this clause, 'Genetic Clinic' includes a vehicle, where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used.

(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;

The terms 'ultrasound clinic' and 'imaging centre' used in Rule 3(3)(1)(b) are not defined in the Act or the Rules.

48. 'Pre-natal diagnostic procedures' [used in Section 2(d)], 'prenatal diagnostic techniques' and 'prenatal diagnostic test' are defined in Section 2(i) (j) and (k) of the PNDT Act as under:

(i) pre-natal diagnostic procedures means all gynecological or obstetrical or medical procedures such as ultrasonography foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, embryo, blood or any other tissue or fluid of a man, or of woman before or after conception, for being sent to a Genetic Laboratory or Genetic Clinic for conducting any type of analysis or pre-natal diagnostic tests for selection of sex before or after conception;

(j) pre-natal diagnostic techniques includes all pre-natal diagnostic procedures and pre-natal diagnostic tests;

(k) pre-natal diagnostic test means ultrasonography or any test or analysis of amniotic fluid, chorionic villi, blood or any tissue

of a pregnant woman or conceptus conducted to detect genetic or metabolic disorders or chromosomal abnormalities or congenital anomalies or haemoglobinopathies or sex-linked diseases;

49. Though the words ultrasound clinic/imaging centre are not defined as aforesaid but it follows from a conjoint reading of definitions aforesaid that any clinic/institute/hospital/nursing home or other place, though not proclaiming itself to be carrying out pre-natal diagnostic procedure and thus not a genetic clinic but having ultrasound or other machines 'capable of' viewing/imaging the foetus and other organs of human body for selection of sex before or after conception, would be covered thereby.

50. We may in this regard highlight that the definition of genetic clinic in Section 2(d) of the Act, as per the Explanation thereto includes a place where ultrasound or imaging machine 'capable of' determining sex of the foetus or having potential for detection of sex during pregnancy or selection of sex before conception is used. The explanation being 'inclusive', cannot be confined to vehicle. This becomes further evident from Section 18(1), which also uses the word 'capable of' and is as under:

18. Registration of Genetic Counselling Centres, Genetic Laboratories or Genetic Clinics:

(1) No person shall open any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, including clinic,

laboratory or centre having ultrasound or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus and sex selection, or render services to any of them, after the commencement of the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 unless such centre, laboratory or clinic is duly registered under the Act.

51. The Act thus takes within its sweep all places/vehicles where ultrasound machine or other machine are kept, whether for prenatal diagnostic procedures or not, if they are capable of sex determination. We will deal further with this aspect in the discussion under question 'C' framed by us in para 41 above.

52. That brings us back to, whether Rule 3(3)(1)(b) is inconsistent with Section 2(p) for the reason of expanding the definition of sonologist as given in Section 2(p) of the Act.

53. Rule 3(3)(1)(b) prescribes the qualifications for setting up of or for employment in a genetic clinic /ultrasound clinic/imaging centre.

54. Though the PNDT Act in Section 2(p) defines the words sonologist or imaging specialist but there is thus nothing in the Act to indicate what a sonologist or imaging specialist as defined in the PNDT Act can do or what he/she is prohibited from doing. There is absolutely nothing in the Act entitling a sonologist or imaging specialist, as defined therein, to use/operate *W.P.(C) Nos.6968/2011, 2721/2014 & 3184/2014* Page 49 of 83

a ultrasound machine or imaging machine or to set up a genetic clinic / ultrasound clinic/imaging clinic. In fact the word sonologist, besides in Section 2(p), is used only at two other places in the Act i.e. in Section 16A(2)(f)(v) while prescribing the categories of persons from whom members of the State Advisory Board are to be appointed and in Section 23(3) while prescribing the punishment for a person who approaches any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or Ultrasound Clinic or Imaging Clinic or a medical geneticist, gynaecologist, sonologist or imaging specialist or registered medical practitioner or any other person for sex selection. The word imaging specialist is used only in Section 23(3). The said provisions do not vest any right in sonologist or imaging specialist as defined in Section 2(p) to set up or seek employment in a place having ultrasound or like machine. On the contrary the Act, by Section 32(2)(i) empowers the Central Government to make rules providing for the minimum qualification for persons employed in genetic clinic and which as aforesaid would include ultrasound clinic and imaging clinic and in exercise of which power Rule 3(3)(1)(b) has been enacted.

55. The question thus, of Rule 3(3)(1)(b) being inconsistent with Section2 (p) does not arise.

56. We may at this stage deal with the contention of senior counsel for the petitioner in WP(C)No.2721/2014 of the words "registered medical practitioner" in Rule 3(3)(1)(b) referring to registered medical practitioner as defined in Rule 2 (ee) of the Drugs and Cosmetics Rules, 1945. We do not find any merit therein because 'registered medical practitioner' is defined in Section 2(m) of the Act as under:

(m) registered medical practitioner means a medical practitioner who possesses any recognised medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956, (102 of 1956), and whose name has been entered in a State Medical Register;

and Rule 2(f) is as under:

2.(f) words and expressions used herein and not defined in these rules but defined in the Act, shall have the meanings, respectively, assigned to them in the Act.

57. That brings us to question 'C' framed by us in para 41 above. There are two limbs of it i.e. whether the insistence in Rule 3(3)(1)(b) read with Rule 6(2) of the Six Months Training Rules on six months training or one year experience coupled with passing the competency test is arbitrary, and if not, whether the insistence thereon even for those intending to or using the ultrasound machines or imaging machines for purposes other than pre-natal diagnostic procedures is arbitrary.

58. Rule 3(3)(1)(b) refers to a Sonologist or Imaging Specialist and which words, in terms of Rule 2(f) supra would take their colour from their definition of Sonologist or Imaging Specialist in Section 2(p) of the Act. In this context the challenge in W.P.(C) No.6968/2011 to Section 2(p) becomes relevant. It remains unrebutted that in the Schedule to the MCI Act there is no "post-graduate qualification, in ultrasonography or imaging techniques" referred to in Section 2(p). The reference certainly cannot be to any such qualification which is not recognised by MCI. Section 2(p) thus indeed is faulty to the said extent and none can claim under Rule 3(3)(1)(b) on the basis of having a postgraduate qualification in ultrasonography or imaging techniques, till such qualification is included in the schedule to the MCI Act.

59. Rule 3(3)(1)(b), even prior to amendment with effect from 9th January, 2014, referred to six months training or one year experience in sonography or image screening. There admittedly was no prescribed six months training or prescription for one year experience. It however appears that registrations under the PNDT Act were being granted on the basis of training / experience with any other person registered under the Act and certificate issued by that person and there was a lot of arbitrariness as was

noticed in *K.L. Sehgal* supra. However since in the absence of any prescription, the reference to six months training or one year experience was not an impediment to anyone obtaining registration, the occasion for challenging the same did not arise. It was rather the grievance of the petitioner in W.P.(C) No.6968/2011 that taking advantage of the faulty definition of Sonologist or Imaging Specialist as aforesaid in Section 2(p) and the absence of any prescription / rules regarding six months training and one year experience, those not competent to set up a ultrasound clinics, had obtained registrations under the Act, defeating rather than serving the purpose of the Act.

60. However upon the framing of Six Months Training Rules and the amendment of Rule 3(3)(1)(b) with effect from 9th January, 2014, the cause of action as per contentions aforesaid has accrued.

61. The respondent UOI has attributed the said amendments solely to *K.L. Sehgal*.

62. Since the respondents in their counter affidavits have extensively referred to *K.L. Sehgal*, notice at this stage may be taken thereof. The learned Single Judge was therein concerned with rejection of the application of doctors of two well-known established radiology / ultrasound clinics of

Delhi for grant / renewal of their registration under the PNDT Act. This Court in the judgment took notice of the stand of the MCI (i) that the recognised medical qualification as defined under Section 2(h) of the MCI Act means any of those medical gualification included in the Schedule to the MCI Act; (ii) that the MCI had framed the Post-Graduate Medical Education Regulations, 2000; (iii) that as per Rule 10 of the said Regulations, the period of training for the award of degree of Directorate of Medicine (MD) / Master of Surgery (MS) consists of three completed years including the period of examination; (iv) that for award of a post-graduate diploma, there is to be two completed years training, including the period of examination; (v) that the specialities in which post-graduate degrees / diplomas can be awarded are prescribed in the Schedule to the Regulations; (vi) that the said Schedule includes qualification of MD with speciality in radio-diagnosis; (vii) that the Schedule also includes diplomas in radiodiagnosis, radiotherapy and radiological sciences; (viii) that the institutes from where the petitioners in that case claimed to have undergone training were not included in the Schedule or in the list of institutes recognised / permitted by MCI to conduct any post-graduate courses in radio-diagnosis or ultrasound; and, (ix) that the petitioners thus could not claim to be having

six months training or one year experience.

It was also noticed in *K.L. Sehgal* that MCI did not appear to be 63. itself aware of medical colleges which provide training in ultra-sonography and diagnostic ultrasound and that there was uncertainity in applying the PNDT Act and the Rules and that none of the authorities were clear, what should be minimum criteria regarding training, where the training should be provided, whether the criteria should be made prospective and so on. It was however observed that these were technical aspects on which the views of the experts rather than of the Court are relevant and that the Court in exercise of jurisdiction under Article 226 of the Constitution lacks the competence to determine such technical issues. This Court lamented on the disconcerting state of affairs resulting in mushrooming growth of diagnostic clinics and ineffective regulation thereof. It was directed that to avoid any confusion, the requirements in terms of qualification, training and experience to be recognised and registered as a sonologist should be incorporated in the PNDT Act and further explicated under the PNDT Rules.

64. It would thus be evident that this Court in *K.L. Sehgal* did not return any findings on which the respondent no.1 could have based its amendment

with effect from 9th January, 2014. The justification of the amendment thereon is thus misconceived.

65. Else, the challenge thereto in these petitions has not been met. No source of power from any of the provisions of the PNDT Act has been shown, to in exercise of power under Section 32, lay down and prescribe the course and training and content thereof to practise medicine with aid of ultrasound machine and to prohibit those, who by virtue of their name entered in the Medical Register under Section 15 of the MCI Act entitled to so practise, from so practising without undergoing the said six months course or experience coupled with passing the competency test.

66. Sections 3, 3B and 4 of the PNDT Act are as under:

3. Regulation of Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics.- 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 prenatal diagnostic techniques;

(2) no Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess qualifications as may be prescribed;

(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;

•••••

3B. Prohibition on sale of ultrasound machines, etc., to persons, laboratories, clinics, etc. not registered under the Act.- No person shall sell any ultrasound machine or imaging machine or scanner or any other equipment capable of detecting sex of foetus to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or any other person not registered under the Act.

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);

(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;

(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;

67. The aforesaid provisions of the Act read with Section 18(1) thereof reproduced earlier prohibit doing of activities mentioned therein without registration under the PNDT Act and the PNDT Rules *inter alia* lay down the conditions for such registration. Registration under the Act and the Rules is thus a licence to carry on the activities which are prohibited by the Act.

68. The said activities which are prohibited by the Act save with licence in accordance with Rules, we have no doubt are activities of practise of 'medicine' defined in Section 2(f) of the MCI Act as under:

> "2(f). "medicine" means modern scientific medicine in all its branches and includes surgery and obstetrics, but does not include veterinary medicine and surgery"

and the licence granted is a "medical qualification" which confers on the grantee / recipient, the right to practise the said field of medicine and in which he / she cannot practise without such registration / licence.

69. The MCI Act, vide Section 10A(1)(b)(i) thereof prohibits a medical college from opening a new or higher course of study or 'training' which would enable a student of such course or training to qualify himself for the award of any recognized medical qualification and which is defined in Section (h) thereof as a qualification included in the Schedules to the said Act. It is not the case that the six months training under the Six Months Training Rules framed therefor under the PNDT Act has been included in the Schedules to the MCI Act. It is thus not a recognized qualification.

70. The Indian Medical Degrees Act, 1916 vide Section 2 thereof describes 'western medical science' as western method of allopathic medicine, obstetrics and surgery but not including Homeopathy or Ayurvedic or Unani System of medicine. Section 3 of the said Act provides that the right to confer degrees, diplomas, licences, certificates or other documents stating or implying that the holder, grantee or recipient thereof is qualified to practise western medical science is only of the authorities specified in Schedule thereto. Section 4 thereof prohibits unauthorized conferment of degrees, diplomas, licences, certificates or other document stating or implying that holder thereof is qualified to practise western medical science.

71. In our opinion, the activities prohibited by the PNDT Act save with licence / registration under the said Act and Rules framed thereunder, are activities of practise of western medical science within the meaning of the Indian Medical Degrees Act and the Appropriate Authority constituted under the PNDT Act which has been empowered to grant registration / licence thereunder having not been included in the Schedule to the Indian Medical Degrees Act, the registration / licence granted by the Appropriate Authority under the PNDT Act cannot thus confer a right to practise what is

prohibited by PNDT Act. On the contrary, as aforesaid a person holding a qualification recognized under the MCI Act was / is entitled to practise what has been taken away / prohibited by the PNDT Act. We agree with the petitioners that the MCI is the sole repository of education in western medical science which includes training and the training if any required for conducting prenatal diagnostic procedures has to be by inclusion in the Schedules to the MCI Act. The Supreme Court in MCI Vs. State of Karnataka (1998) 6 SCC 131 reiterated in Dr. Preeti Srivastava Vs. The State of Maharashtra (1999) 7 SCC 120 held that fixation of admission capacity in medical colleges/institutions is the exclusive function of MCI and the same has a direct nexus with co-ordination and determination of standards in medical education. Though undoubtedly the permission under the MCI Act, for establishment of a medical college is not applicable to Central Government (see Explanation 1 to Section 10A) and permission for starling a new course of study or training is to be granted by the Central Government but the MCI having been constituted under the MCI Act as the expert body to make recommendations to the Central Government, we are of the view that the need even if felt for six months training as under the PNDT Act, should be fulfilled within the confines of the MCI Act. We do

not find any representation of the MCI in the Supervisory Boards or in the Appropriate Authorities or Advisory Committees constituted under the PNDT Act to advise the Central Government on policy matters thereunder and implementation thereof. Though the respondent UOI claims to have constituted MCI before the amendment of 9th January, 2014 but the said consultation cannot be a substitute for the procedure required to be followed under the MCI Act.

72. The purport of our above discussion is to again highlight that the essential provisions of the PNDT Act i.e. those directly concerned to serve the aim and objective thereof, appear to have been diluted and / or lost their effectiveness in the midst of provisions which do not appear to have any nexus to the aim and objective of the Act, leading to the child sex ratio continuing to fall except in some metropolitan cities.

73. There is no denying the fact that ultrasound machines today are used for diagnosis of ailments of a large number of organs in the human body and the use thereof is not limited to pre-natal diagnostic procedures.

74. Though the PNDT Act is concerned with use of ultrasound machines only in pre-natal diagnostic procedures and not with use thereof for other diagnostic procedures and there is merit in the grievance of the petitioners, of the Doctors using the ultrasound machines for other diagnostic procedures having also been brought in the purview of the Act and being required to comply with cumbersome requirements thereof, to their detriment and cost, but at the same time the reason for the net of the Act having been spread far and wide to encompass all ultrasound machines, because an ultrasound machine even though not intended for prenatal diagnostic procedures being 'capable of' use therefor, cannot be said to be baseless. We are therefore unable to confine the operation of the PNDT Act only to those proclaiming to run a genetic clinic and hold that all those places including vehicles where ultrasound or like machine 'capable of' sex determination is kept would be a genetic clinic and within the ambit of the Act.

75. It was to balance the said conflicting interests that we had enquired of the technical solution if any, to prevent use of ultrasound machines not intended for prenatal diagnostic procedures, therefor and suggested, though registering all users of ultrasound machines but exempting those furnishing declaration not to use the same for prenatal diagnostic procedures from complying with other requirements of the Act but remaining liable for inspection and penalties etc. if found to be violating.

76. Though we were told that neither was / is possible but we find that a Division Bench of the High Court of Bombay in *Radiological and Imaging* Association (State *Chapter-Jalna*) Vs. Union of India MANU/MH/1050/2011 was concerned with a challenge to a circular dated 10th March, 2010 of the District Magistrate Kolhapur whereby all Doctors, Sonologists and Radiologists were called upon to install device "silent observer" in their ultrasound machines, on the ground that the same invaded privacy of the patients and was also contrary to the provisions of the PNDT Act and the Rules which merely required the doctors to maintain records. It was the defence of the District Magistrate, Kolhapur that the requirement for maintaining records and the provision for inspection thereof by the authorities was failing to check the child sex ratio which was continuing to fall and the "silent observer" if installed in the ultrasound machines will capture and store the video record of each sonography test enabling the authorities to effectively check violations. The Central Government also supported the said stand. The High Court found that the images stored in the "silent observer" remain part of the ultrasound machine on which "silent observer" is embedded and enables the authorities under the Act to detect violation of the PNDT Act by removing the "silent observer" from the

ultrasound machine and accessing the sonographies done with the ultrasound machine on a computer. The challenge on the ground of breach of privacy was negatived reasoning that the doctors were in any case required to maintain the record and the petition was dismissed. We also find that during the hearing of another petition before the Bombay High Court impugning the ban on use of portable ultrasound machines and as reported in the judgment therein i.e. Radiological and Imaging Association (State Chapter) Vs. Union of India MANU/MH/1436/2011, the Advocate General for the State of Maharashtra stated that the order as issued by the District Magistrate, Kolhapur was applicable to the entire State of Maharashtra and the advocate appearing for the Ministry of Health, Union of India also stated that the said direction for installation of "silent observer" is in accordance with law and directions to the said effect shall be issued with respect to the rest of the country as well. We yet further find another Division Bench of the Bombay High Court in Writ Petition Lodging No.2059/2012 titled Dr. Rajendra G. Goyal Vs. State of Maharashtra to have vide order dated 17th September, 2012 stayed the ban on use of portable ultrasound machines subject to installation of "silent observer" therein.

77. We are at a loss why neither party informed us of the same and rather inspite of our specific enquiry ruled out such a solution. In our opinion the installation of silent observer on ultrasound machines offers perfect balancing of the need to prevent misuse of ultrasound machines for sex determination and the need to not burden the doctors desirous of using ultrasound machines for procedures other than pre-natal with unnecessary paper work and displaying warnings in their clinics as required to be displayed by genetic clinics.

78. We further find that a Division Bench of the High Court of Kerala in *Qualified Private Medical Practitioners and Hospitals Association Vs. State of Kerala* MANU/KE/0330/2006 was concerned with petitions for a declaration that the laboratories and clinics which do not conduct pre-natal diagnostic tests using ultrasonography will not come within the purview of the PNDT Act and for a direction not to insist for registration of all ultrasound scanning centres irrespective of the fact whether they are conducting pre-natal diagnostic tests using ultrasonography or not. It was contended before the Court that only institutions which use ultrasonography for the purpose of pre-natal diagnostic tests will come within the purview of the Act and only such institutions are required to register with the

Authorities under the Act and the direction to all ultrasound clinics in the city to resister was bad. The respondents of course relied upon the order of the Supreme Court in CEHAT to contend that all clinics with ultrasound machines require registration irrespective of the fact whether the machines were used for any pre-natal detection or not. The High Court held that though Section 18 of the Act compels registration of Genetic Counselling Centres, Genetic Laboratories or Genetic Clinics without which no person can open any such centre, laboratory or clinic but the expression "Genetic Counselling Centre" as defined under Section 2(c) makes it clear that only those institutes, hospitals or nursing homes which provide for genetic counselling to patients come within the ambit of the expression "Genetic Counselling Centre". Further, on a reading of the definition in Section 2(d) of a genetic clinic it was held that only those clinics, institutes, hospitals or nursing homes which conduct pre-natal diagnosis would be covered. It was thus held that those hospitals, nursing homes or clinics not conducting any pre-natal diagnostic procedures though having a ultrasound machine would not be Genetic Counselling Centres or genetic clinics within the meaning of the Act. It was further held on a interpretation of Section 4(1) that the legislature however has extended the prohibition contained therein even to

unregistered counselling centres or diagnostic centres or genetic clinics i.e. even institutions which may not require registration will still be governed by the restrictive provisions and cannot indulge in any activities contrary to the legislative mandate imposed under Section 4 and the prohibitions contained therein equally apply to all such institutions. It was further held that with a view to prevent misuse of any pre-natal diagnostic techniques except for the purpose of genetic or metabolic diseases etc., the authorities would be free to conduct inquiries or to hold inspections at places where such device is available and to take action in case any person or institution is found to have indulged in activities contrary to the provisions of the Act. We do not find the matter to have been taken to the Supreme Court.

79. We also find the High Court of Punjab and Haryana in *Medscan Diagnostic Imaging Centre Vs. State Appropriate Authority* MANU/PH/3702/2014, though concerned with a challenge to an order of seizure of MRI and CT scan gadgets under the PNDT Act to have observed that mere possession of a machine or a gadget capable of detection of sex cannot be an offence under the Act. It was held that this would set new restrictions which will be disastrous for an ordinary clinic which is not registered as a genetic clinic but has an MRI or CT scan for the purposes of determination of other abnormalities that may have no reference at all to performance of sex determination. It was held that possession of equipment ought not to be taken as possession of equipment which could be used for sex determination. The Court took notice of the poor detection of violations of the Act but observed that the same cannot be a ground for punishing mere possession of the machine without any charge of having conducted sex determination with the aid thereof. LPA No.696/2015 preferred thereagainst was dismissed vide judgment dated 7th May, 2015. We again do not find the matter to have been taken to the Supreme Court.

80. From the above, it appears that there is no uniformity in the implementation of the Act and the Rules across the country and no attempt even towards the same has been made.

81. We have hereinabove on an analysis of the provisions of the PNDT Act held that the same is not concerned with formulating education or qualifications for practising medicine with the aid of ultrasound machine. The power of the Central Government under Section 32 to make rule providing for minimum qualifications of persons employed at genetic clinic has to be interpreted in the said light. The rule making power under a statute cannot travel beyond the Act. There is no provision in the Act providing for imparting of education including training or formulating curriculum thereof or to hold competency test, as a pre-requisite to registration under the Act entitling a person to practise medicine with the aid of ultrasound machine.

82. In the absence of any such provision in the Act, no such power can be conferred by the Central Government on itself in the guise of making rules. Supreme Court in *Academy of Nutrition Improvement* supra cited by the senior counsel for the petitioner reiterated that conferment of rule making power by an Act does not enable the rule making authority to make a rule which travels beyond the scope of enabling Act.

A Division Bench of this Court, in Indraprastha Gas Ltd. Vs. 83. & **Petroleum** Natural Gas *Regulatory* Board (PNGRB) MANU/DE/2313/2012, for the detailed reasons given therein and need to repeat which herein is not felt, held that the Petroleum & Natural Gas Regulatory Board Act, 2006 does not confer any power on the PNGRB to fix /regulate price of gas as had been done vide the order of the PNGRB impugned in that proceeding and accordingly held the regulations framed by the PNGRB empowering it to fix the price to be beyond the competence of PNGRB and *ultra vires* the PNGRB Act. Reliance in the judgment was placed on (i) various dicta of the courts that price fixation is a legislative function, to be performed by a statutory authority in furtherance of the provisions of the relevant laws; (ii) *U.P. Power Corporation Limited Vs. National Thermal Power Corporation Ltd.* (2009) 6 SCC 235 holding that regulatory provisions are required to be applied having regard to the nature, textual content and situational context of each statute; and, (iii) *DLF Qutab Enclave Complex Educational Charitable Trust Vs. State of Haryana* (2003) 5 SCC 622 holding that a Regulatory Act must be construed having regard to the purpose it seeks to achieve and a statutory authority cannot ask for something which is not contemplated under the statute.

84. The appeal against the aforesaid judgment of this Court, was dismissed by the Supreme Court vide judgment reported as *Petroleum & Natural Gas Regulatory Board Vs. Indraprastha Gas Ltd.* (2015) 9 SCC 209. Supreme Court also proceeded to examine whether a reading of provisions of the Act showed a conferment of power to fix price and not finding so, upheld the judgment of this Court. The contention, that PNGRB having been established under a statute, to regulate, a power to regulate price should be inferred, was negatived.

85. We are humbly of the view that just like price fixation is a legislative function, similarly, education, particularly higher education as in the field of medicine is a legislative function to be performed by a statutory authority in furtherance of the provisions of the relevant law, just like the MCI constituted under the MCI Act, All India Council of Technical Education (AICTE) constituted under the All India Council for Technical Education Act, 1987, universities constituted under the University Grants Commission Act, 1956 etc. are performing. In the PNDT Act with which we are concerned, though Statutory Authorities viz. Supervisory Boards, Appropriate Authorities and Advisory Committees have been constituted but not empowered to regulate education in the field of medicine with the aid of ultrasound machine. The Central Government, in our view, in exercise of its rule making power under the said Act cannot do so. Supreme Court, in Professor Yashpal Vs. State of Chhatisgarh (2005) 5 SCC 420 held that it is the responsibility of Parliament to ensure that proper standards are maintained in institutions for higher education.

86. In the field of medicine, we find that the Supreme Court in *Hamdard Dawakhana Vs. Union of India* AIR 1960 SC 554 concerned with the challenge to Section 3(d) of the Drug and Magic Remedies (Objectionable

Advertisements) Act, 1954 prohibiting taking any part in the publication of any advertisement referring to any drug in terms which suggests the "diagnosis, cure, mitigation, treatment or prevention of any general disease or any other diseases or condition which may be specified in the Rules made under the Act" held that the delegation to the Administrative Authority without the Parliament establishing any criteria, standards or principles on which a particular disease is to be specified thereunder was beyond the permissible boundaries of valid delegation. It was held that the words, "or any other disease or condition which may be specified under the Rules made under the Act", confer uncanalised, uncontrolled power to the executive and is *ultra vires*.

87. We also find that the Supreme Court in *Godde Venkateswara Rao Vs. Government of Andhra Pradesh* AIR 1966 SC 828 was concerned with a challenge to an order of the Government of Andhra Pradesh under Section 72 of the Andhra Pradesh Panchayat Samithis and Zilla Parishads Act, 1959 on the ground of being inconsistent with the provisions of the Act. It was held that the government in exercise of the rule making power under the Act can only makes Rules for carrying out the purpose of the Act and cannot under the guise of the said Rules convert an authority with power to establish a Primary Health Centre into only a recommendatory body and cannot vest in itself a power which under the Act vests in another body. The Rules to the extent they transferred the power of the Panchayat Samithi to the Government, being inconsistent with the provisions of the Act, were held, must yield to the Act.

88. The matter, in our view is placed beyond any pale of controversy by the two decisions of the Supreme Court relating to the profession of law. Supreme Court in Indian Council of Legal Aid and Advice Vs. Bar *Council of India* (1995) 1 SCC 732 was concerned with the challenge to the Rule introduced by the Bar Council of India prohibiting enrolment as an Advocate of those who had completed the age of 45 years. The Bar Council of India justified the said Rule as the sentinel of professional conduct and the same being necessary for maintaining standards and traced its power to make such a Rule to laying down the conditions subject to which an Advocate shall have right to practise and the circumstances under which a person shall be deemed to practice as an Advocate. It was however held that the power thereunder was to lay down the conditions applicable to an Advocate i.e. a person who has already been enrolled as an Advocate and did not entitle the Bar Council of India to bar the entry into the legal

profession of persons who had completed 45 years of age. It was further held that the Parliament while enacting the Advocates Act, 1961 had provided the basic substantive matters, viz. eligibility for entry into the profession, disqualification for enrolment and had nowhere restricted the entry of those who had completed the age of 45 years as Advocates and the Bar Council of India in the guise of making a Rule could not introduce an additional condition for entry into the profession. Accordingly, the Rule was held to be beyond the rule making power and *ultra vires* the Act.

89. In another case namely *V. Sudeer Vs. Bar Council of India* (1999) 3 SCC 176, the Supreme Court was concerned with the Bar Council of India Training Rules, 1995 as amended by the Resolution of the Bar Council of India in the meeting held on 19th July, 1998, relating to training of entrants of the legal profession. It was the contention of the petitioners that after having successfully completed their legal education by getting requisite law degrees from the Universities, their right to practise law as available to them under the Advocates Act could not be taken away by requiring them to undergo training. It was also the contention that the Rules were totally unworkable, highly unreasonable and discriminatory and violative of Article 14 of the Constitution of India. Finding that under the Advocates Act, not having undergone pre-enrolment training was not a disqualification for enrolment and further not finding any legislative intention in the Advocates Act requiring a law graduate seeking enrolment as an Advocate under the Act to undergo any pre-enrolment training as a condition for enrolment and further finding that under the Advocates Act a person on acquiring a qualification mentioned therein was qualified to be an Advocate, it was held that the general rule making power did not take into its sweep the power to provide pre-enrolment training and examination for applicants who were seeking enrolment as Advocates. It was further held that the power of Bar Council of India over legal education did not extend to laying down preenrolment training. On an analysis of the provisions of the Advocates Act, it was also held that enrolment of Advocates is a task of State Bar Council and not of Bar Council of India and it was axiomatically held that Bar Council of India could not exercise a rule making power thereover. It was explained that the rule making power has to take colour from the statutory function and cannot enable to impose additional restrictions.

90. We respectfully add that the position here is identical. The MCI Act, vide Section 15 thereof confers a right on the person holding a recognised medical qualification and whose name is entered in the Medical Register

maintained thereunder, to practise medicine. The said right is taken away by the impugned Rules made under the PNDT Act which is not enacted to address the issues of education in the field of medicine and does not contain any statutory provisions therefor, by requiring such person to undergo training. The same has but to be held to be not permissible.

91. Supreme Court in Kunj Behari Lal Butail Vs. State of H.P. (2000) 3 SCC 40 also held that in exercise of delegated power to legislate circumscribed by the expression - "for carrying out the purposes of this Act", the State Government cannot bring within the net of the Rules what has been excluded by the Act itself. It was further held that the legislature cannot delegate its essential legislative functions which consist in the determination or choosing of the legislative policy or of enacting that policy into a binding rule of conduct. It was explained that it was very common to the legislature to provide for a general rule making power to carry out the purpose of the Act but while testing the validity of the said Rules, the object and purpose of the enactment is to be found out and only if the Rules fall within the limits prescribed by the parent Act would they be valid. It was further held that the rule making power cannot be exercised to bring into existence substantive rights or obligations or disabilities not contemplated by the provisions of the Act itself. This was reiterated in *Global Energy Ltd*. *Vs. Central Electricity Regulatory Commission* (2009) 15 SCC 570.

92. In the context of interplay between PNDT Act, and MCI Act reference with benefit can be made to **Bharathidasan University Vs. All** India Council for Technical Education (2001) 8 SCC 676 concerned with a need for University created under the Bharathidasan University Act, 1981 to seek the prior approval of the All India Council for the Technical Education for imparting technical education. It was held that when the AICTE Act does not contain any evidence of any intention to belittle and destroy the authority or autonomy of other statutory bodies having their own assigned roles to perform, merely activated by some assumed objects or desirabilities, the AICTE could not intervene. On a perusal of the provisions of the AICTE Act, it was found that AICTE was not intended to be an authority either superior to or to supervise the Universities and was thus held not entitled to make a Regulation in the exercise of its regulation making power, compelling the Universities to seek its prior approval. It was further held that the fact that the Regulations had been laid before the legislature (as is the case with the impugned Rules), did not confer them with any more sanctity or impunity.

93. In our opinion, the position herein is identical. There is nothing in the PNDT Act to show that it interferes in any manner with the MCI Act. What has been permitted by the MCI Act i.e. a right to practise medicine upon acquiring a qualification recognised under the MCI Act and having the name entered in the Medical Register, cannot be taken away by making a Rule under the PNDT Act requiring such persons to undergo training.

94. We therefore hold that the power of the Central Government in exercise of Rule making power under Section 32(2)(i) of the PNDT Act to provide minimum qualifications for persons employed at Genetic Clinics etc does not extended to creating any new qualifications. Central Government thereunder cannot prescribe qualifications other than those recognised by MCI. If the Central Government is of the view that a qualification of MBBS does not educate/equip a person to practise medicine with aid of ultrasound machine, it can prescribe any other qualification viz. M.D. (Radiology)/ M.D. (Obstetrics), M.D.(Gynaecology) as the minimum qualification under Section 32(2)(i) of PNDT Act. If the Central Government is of the view that none of the qualifications recognised by MCI so equip a person, the remedy therefor is to prescribe such qualification under the MCI Act.

95. Though in our opinion, MCI under Section 20A of the MCI Act is fully

empowered also to prescribe the professional conduct to be observed by persons working in places where ultrasound machines are used but the Act having made, what was earlier not an offence, an offence, the Central Government in exercise of power under Section 32 would in our view be entitled to prescribe such conduct. However the same, again in view of above cannot take the form of a training or course required to be undergone before registration under the PNDT Act but in the form of 'Do's' and 'Don'ts' and of which patients visiting Genetic Clinics can also be made aware by requiring such clinics to display the same prominently and press releases etc.

96. Though we have on an interpretation of the provisions of the PNDT Act held hereinabove that for proper implementation and enforcement of the Act all places having ultrasound or like machines 'capable of' sex determination require registration under the Act but at the same time we are unable to interpret the provisions of Sections 4,18,29 of PNDT Act and Rules 2(2), 3(2), 9 of the PNDT Rules requiring Genetic Clinics etc to comply with requirements mentioned therein, as extending to those places where a ultrasound of like machine 'capable of' sex determination exists but not for conducting prenatal diagnostic procedures. To interpret/hold

otherwise would tantamount to extending the application of the PNDT Act to persons and places for whom/which it was not intended. We find merit in the contention of petitioners that ultrasound as a diagnostic tool has application for procedures other than pre-natal also and requiring places having ultrasound machines 'capable of' determining sex but not intended and used for prenatal diagnostic procedure to also comply with requirements of a genetic clinic serves no purpose. We are afraid, it may raise cost of medical treatment and put a unnecessary strain on doctor-patient relationship. Supreme Court recently in Lal Shah Baba Dargah Trust Vs. Magnum Developers MANU/SC/1437/2015 reiterated Mangin Vs. IRC (1971) 1 All ER 179 (PC) laying down that the object of the construction of a Statue being to ascertain the will of the legislature, it may be presumed that neither injustice nor absurdity was intended – if therefore a literal interpretation would produce such a result and the language admits of an interpretation which would avoid it, then such an interpretation may be adopted. We are of the view the language of the Act and the Rules permits an interpretation, though making registration mandatory for possessing a ultrasound or like machine 'capable of' determining sex but not mandating fulfilment of the provisions of the Act and the Rules for use thereof for

prenatal diagnostic procedures, if not used therefor.

97. We, in this respect concur with the view aforesaid of the High Courts of Bombay, Kerala and Punjab and Haryana and adopt the same.

98. We accordingly dispose of these petitions with the following declarations / directions:

- (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 recognised by MCI and the PNDT Act does not empower the statutory bodies constituted thereunder or the Central Government to devise and coin new qualification;
- (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;
- (iii) However, if the person seeking registration (a) makes a declaration in the form to be prescribed by the Central *W.P.(C) Nos.6968/2011, 2721/2014 & 3184/2014*

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 Centre;

- (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;
- (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 the time to time and in such manner as may be prescribed by the Central Supervisory Board; and,

(vi) Rule 3(3)(1)(b) of the PNDT Rules (as it stands after the amendment with effect from 9th January, 2014) is *ultra vires* the PNDT 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.

No costs.

RAJIV SAHAI ENDLAW, J.

CHIEF JUSTICE

FEBRUARY 17, 2016 'bs'/pp/gsr..