COMMENT

The Oxytocin ban: The judgment and legal issues

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Abstract

This paper primarily discusses the judgment of the Delhi High Court on the government's ban on the use of Oxytocin. Part 1 recapitulates the events leading up to the ban and Part 2 discusses the legal issues considered by the Court before pronouncing its judgment. The paper outlines how life and death issues caused by the ban on a drug have finally been settled by legal considerations, apparently obscure to the non-specialist, but necessary to be understood by health policy makers.

Oxytocin: Background to the ban

The issue

The Delhi High Court bench of Justices Ravindra S Bhat and AK Chawla pronounced on December 14, 2018, its final order (1) on Oxytocin, quashing the notification (hereafter the impugned notification) (2) that had banned the manufacture and sale by private manufacturers of Oxytocin. The ban also covered ampoules for domestic use; and restricted manufacture to only the public sector undertaking (PSU), Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL). KAPL had no previous experience of producing Oxytocin. In fact, it was granted a manufacturing license for Oxytocin ampoules as late as April 2018 (1: para 123) It was envisaged that KAPL would directly supply the drug through a countrywide cold chain, only to registered hospitals and clinics in the public and private sectors. The related measures proposed by the government included not allowing retail or wholesale chemists to stock Oxytocin in their shops in any form or name (2).

Oxytocin is an essential and life-saving drug frequently used for women during childbirth, for the induction and augmentation of labour, to make childbirth safe and prevent death resulting from postpartum haemorrhage (PPH). PPH contributes 38% — approximately a total of 32,000 maternal deaths — of all maternal deaths (3, 4) occurring every year in India. A recent report from the Registrar General of India (RGI) showed that nearly 4 women die every hour in India from complications developed during childbirth, with heavy blood loss caused by haemorrhage being a major factor (3, 4). Oxytocin is also important in a practice called "active management of third stage labour" (AMTSL). Since it cannot be predicted with certainty beforehand which woman is going to develop PPH after delivery, all standard guidelines, both internationally (WHO) (5) and in India (GOI) (6) recommend that the practice of AMTSL should be performed universally for all women, ie, every woman should get a shot of Oxytocin immediately after the birth of the baby in order to prevent PPH. The guidance note of the Maternal Health Division, Ministry of Health and Family Welfare on prevention and management of postpartum haemorrhage recommends AMTSL for prevention of PPH and states that: "Oxytocin remains the uterotonic of choice for AMTSL. Oxytocin (10 IU, IM) is the preferred uterotonic based on studies on the safety and effectiveness of uterotonics. It also is the recommended uterotonic drug for PPH prevention during caesarean sections." (6). A uterotonic, is an agent used to induce contraction or greater tonicity of the uterus.

The immediate trigger for the series of orders leading up to the impugned notification (2) was its purported misuse and consequent threat to the health and well-being of milch cattle. The injection of Oxytocin into cattle was feared to leave residues of the drug in the milk produced, which was considered harmful to human health.

Petitioner AIDAN cited studies by scientists from the Indian Council of Agricultural Research (7) and National Dairy Research Institute (8) that showed that there was no evidence to support this apprehension.

The AIDAN petition also argued that Oxytocin, an essential and life-saving medicine, needed for preventing deaths of mothers, during and immediately after delivery, which was relatively easily available, would become scarce. AIDAN argued that in a country where more than half of all pregnant women are anaemic and with several states still unable to assure blood availability at all major delivery points, this would make women even more vulnerable and would lead to many more maternal deaths (1: Para123). The ban order was therefore entirely disproportionate to the alleged harms. Never before has any essential drug included in the WHO Essential Drug List and in the National List of Essential Medicine (9) been dealt with in such a biased, manner, and with such insouciance.

The Court noted that the interests of the sole bulk drug producer of Oxytocin in India, Hemmo Pharma, were not

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disturbed, and it could, even if the impugned notification had gone through, still manufacture for export, as could the licensed formulation manufacturers. Hemmo Pharma produced annually 22 kg out of which only 2 kg was used for annual domestic production of 6 crore ampoules while the remaining 20 kg (equal to 66 crore ampoules) was exported. Therefore, as the Hon'ble Court opined, "The arbitrary nature of the impugned prohibition is starkly apparent." (1: Para 130).

The other petitioners who were manufacturers – BGP Products Operations GMBH (a subsidiary of Mylan) and others – invoked Article 14 (right of equality before law) and Art 19 (1) (g) (right to practise any profession, or to carry on any occupation, trade or business) of the Constitution of India and submitted that the impugned notifications were violative of these provisions, arguments essentially accepted by the Hon'ble Delhi High Court as we shall see.

The Union of India preferred to fall back upon Article 19(6) of the Constitution of India to justify its reservation of Oxytocin manufacture to the public sector even as it tried to highlight the supposed dangers to cattle and vegetables, and to girl children in sex trafficking.

Influential animal rights lobby leads to a bad decision

The Court noted that the several minutes of the Drug Technical Advisory Board (DTAB) and the Drugs Consultative Committee (DCC) (available at https://cdsco.gov.in/opencms/opencms/en/dcc-dtab-committee) nowhere recommend a ban on private manufacture and sale of Oxytocin nor suggest confining it to PSUs, or for that matter, to a single PSU. Neither could the Union of India produce satisfactory evidence of "widespread misuse" of Oxytocin (1: para 123). All the statutory body meetings "recommended against the ban of sale of Oxytocin having regard to its beneficial medical effects…." The 67th and 70th meetings of the DTAB; the 49th and 69th meetings "consistently and clearly stated that Oxytocin could not be banned or prohibited as it has a defined use for therapeutic purposes." (1: Para 123 (iv) and (v)).

The decision to ask KAPL to be the sole manufacturer of Oxytocin in India was taken despite several notings in the government files requisitioned by the Delhi High Court to be produced – these notings doubted the capability and viability of KAPL to execute the role of sole manufacturer of oxytocin formulations (See 1: Para 123(xx)).

Smt. Maneka Gandhi, the Minister for Women and Child Development of the NDA Government, used her political clout in the matter to influence various levels of decision making. On October 16, 2015, the 49th meeting of the DCC was addressed by Smt. Maneka Gandhi highlighting the negative consequences of misuse of oxytocin for milch cattle. (mentioned inter alia in 1: Para 42)

The minutes of the 78th meeting of the DTAB held on February 12, 2018 recommended restricting sale of Oxytocin to hospitals in the public and private sector but not a total ban on private manufacture (1: Para123). By February 28, 2018, the decision to ban had been taken and a public notice of the Government's intentions was issued. (In fact, a High-Level Group meeting of February 8, 2018 had already taken the decision to ban private manufacture of Oxytocin once production of Oxytocin ampoules by KAPL was in full swing. (1: Para 123 (xxiii))

This shows that, if anything, the decision to ban was taken in spite of research evidence and expert opinion to the contrary. Also, it is ironic that in the run up to the ban, the Minister whose primary remit was, and is, Women and Child Development, did not show as much concern for the deaths of women in childbirth as she did for cattle and vegetables. A greater sense of balance would have been desirable in a Union Minister.

Himachal Pradesh High Court judgment: The "tipping point"

The judgment of the Himachal Pradesh (HP) High Court dated 15.03.2016 [CWPIL No. 16 of 2014, Court on its own motion v. State of Himachal Pradesh and others] (10) proved to be *"the tipping point."* (1: Para 109, italics in original)

The judgment was a result of the HP High Court taking suo moto cognisance of a report of Oxytocin misuse in animals (10) in the Hindi newspaper *Amar Ujala* dated Nov 9, 2014. The crucial part is the direction issued in Para 21 (ix) of the HP High Court judgment wherein it directed the government "to consider the feasibility of restricting the manufacture of Oxytocin only in public sector companies and also restricting and limiting the manufacture of Oxytocin by companies to whom licenses have already been granted," a suggestion made by the amicus curiae and one that was conveniently interpreted as a mandate for confining Oxytocin manufacture to the public sector.

The HP bench in issuing directions "did not consider the therapeutic uses of Oxytocin in human beings and its critical role in pregnant women, particularly at the post- partum stage to stem haemorrhage." (1: Para 123 (xvi))

Instead the HP High Court chose to focus on the alleged misuse and harmful impacts of Oxytocin on milch cattle, milk and vegetables (10).

Legal issues in the Delhi HC final order

Considering the various issues narrated above, the bench of Justices Bhat and Chawla decided in its wisdom that the following questions were worthy of determination in the batch of writ petitions challenging the Oxytocin ban and related restrictions:

1. Does the impugned notification, namely, GSR 411(E) dated 27.04.2018 (2), fall within the scope of Article 19(6) of the Constitution of India?
2. Is the impugned notification *ultra vires* of the provisions of the Drugs (and Cosmetics) Act?
3. Whether the impugned notification is arbitrary and therefore, unsustainable?

Impugned notification and scope of Article 19(6) of the Constitution of India

Article 19 outlines six freedoms. Specifically, Art 19 (1) (g)[1] asserts the right to trade/any profession/business. The proposed ban would have shut down domestic Oxytocin production and sales of all licensed private sector manufacturers. And with it the right enshrined in Article 19 (1) (g) would have been infringed. An exception is however made through Article 19 (6) (ii) which asserts the right of the State to reserve, in the public interest, certain products/business/ trade for the public sector as part of "reasonable restrictions" on the right to trade, etc. Article 19 (6) (ii) basically legitimises state monopoly and seemingly puts it beyond judicial review. Counsel for the government cited several related cases in support of the restrictions/ban on the manufacture/ sale of Oxytocin which de facto led to state monopoly over manufacture and sale of Oxytocin formulations. While the judgment interrogates the logic and relevance of these cases cited by the government and their appropriateness to the argument, it does not question in any way the right of the Government to create such a monopoly. The judgment also appears to quote with approval certain case laws[2] that argue that public interest is to be assumed, unless the contrary is shown, if the action of the State results in monopoly.

The impugned notification cites Section 26 A of the Drugs and Cosmetics Act (11)[3] to promulgate the prohibition of private manufacture. However, as the Delhi High Court judgment points out after detailed examination, "no provision in the enactment (Drugs and Cosmetics Act) *per se* authorizes the taking over of the drug business or an entire line of business for monopoly production by one licensee – even if it were a State monopoly." (1: Para 79)

And further:

> …. *Any provision or law which does not enable the creation of a monopoly either directly or authorize the creation of State monopoly, therefore, does not fall within the productive ambit of Article 19(6)(ii). In the present case, this Court is of the opinion that Section 26A does not and cannot be considered by any standard or interpretation as a law that creates State monopolies or enables the creation of State monopolies. Consequently, the Union's arguments on this score are unsustainable and have to fail*. (1: Para 82)

So, in the instant case the State cannot – as per the order – claim immunity under Art 19 (6).

A fine distinction

But here is a fine, if confusing, distinction that the judgment seeks to make. What if we ask the question: Is the ban order per se beyond the powers (*ultra vires*) of Section 26A of the Drugs and Cosmetics Act (11) which empowers the Central Government "to prohibit manufacture etc of drug and cosmetics in public interest"? Their Lordships after an extensive discussion (1: Paras 83 to 90) on the implied meanings of decisions that are regulatory, restrictive and prohibitive, conclude that:

> …*in a given, or suitable case, the power to "restrict" or "prohibit" can be used by the Central Government, under Section 26A to partially ban the manufacture of a drug, ie prohibit its production by private manufacturers, and reserve it, so to speak for the public sector. The measure - ie the impugned notification cannot, therefore, be said to be ultra vires the power under the statute.* (emphasis in original)

But again, we have not completely examined Section 26 A. Section 26 A talks of prohibiting (that is banning), restricting or regulating a drug only if it has unacceptable safety (risk to human beings or animals), or lacks efficacy (does not have the therapeutic value claimed/purported to be claimed), or the content of the drug has no therapeutic justification. And it needs to use relevant material in determining so, and such actions have to be in public interest. (11: Sec 26A)

From the relevant material examined by the Court (1: Paras 100-2) including several minutes of DTAB/DCC and after noting that it is part of the NLEM and the WHO Essential Medicines List, as also WHO recommendations for prevention and treatment of postpartum haemorrhage (12), and after taking into account Oxytocin's vital role on saving the lives of pregnant women in PPH, the Hon'ble Court observed:

> … *it is apparent, that the materials on record, as well as the materials produced in the form of official files, do not point to any known or established risk to human or animal life, on account of Oxytocin use. On the other hand, its use for medicinal and therapeutic purposes is known and recognized …. As to the beneficial use – even necessity of Oxytocin, the (maternal mortality) figures, in a sense speak for themselves …... The Central Government stated, in Parliament, that the largest cause of maternal deaths is haemorrhaging which accounts for 38% of all maternal deaths. According to UN data, India is estimated to account for 15% of the total global maternal deaths. It would be a fair, or reasonable assumption that ease of access to Oxytocin was one of the reasons for the significant decline in maternal deaths due to haemorrhaging*. (1: Paras 103-5)

The impugned notification therefore cannot be seen to be valid in the light of the provisions of Section 26 A and powers exercisable under it.

Shoddy data

Their Lordships also noted that none of the data produced by the Government in court warranted a conclusion by the Central Government that Oxytocin was misused in a manner that necessitated a ban on domestic manufacture and sale by the private sector (1: Paras 106-8).[4]

If anything, in this writer's opinion, the data submitted to the Court was skimpy, shoddy and non-sequitur and spoke of a half-hearted attempt, probably a consequence of rational and conscientious officials (at least most of them) forced to

defend, under pressure from above, the indefensible. The Court's opinion (1: Paras124-7) of the indifferent quality of the data presented by the Union of India is exemplified with observations like:

> *124. The action banning licensed manufacturers must be premised on data showing that licensed manufactures are misusing their licences and engaging in illegal import, manufacture, distribution or sale of the drug. In the entire counter affidavit there is not a single instance established, of such misuse by any licensed manufacturer… These facts do not show that the action of a complete prohibition for domestic manufacture of Oxytocin, an essential drug, by indigenous valid license holding manufacturers, was called for….*
>
> *125. Furthermore, the UOI did not consider the fact that not all manufacturing units would have the same manufacturing loss factor; some may be more efficient….*
>
> *126. … Now, the origin of this data is not explained; furthermore the table talks of 45 licenses being suspended. However, the chart preceding this one, says that over 100 licensees are permitted to manufacture Oxytocin. Therefore, whether the 45 licenses suspended is of the manufacturers, or pharmacists or dairies is unknown. Also, even if the seizures of 1.5 kg of API is correct, the culprits are known. The UOI does not say who is or are those culprits. …. Moreover, the fact that of those figures 1.5 kg was seized in one year (2015-16); in the preceding two years, the seizures were far less, thus showing lack of any emergent necessity for the prohibition.*
>
> *127. This court has discussed the charts, particularly the last one, despite the fact that the UOI did not offer any explanation regarding the source of it. Statistics, unless explained, can be highly misleading. Therefore, unless the details of raids and other connecting materials are disclosed, the bare statistics (without explanation) proves little.* (Extracts from Paras 124-127, emphasis ours)

Subordinate legislation and judicial scrutiny

Duty bound to defend a weak case, the Government counsel opened a third legal window, a red herring that demands a nuanced response as the courts have opined variously. The Union of India argued that the notification under Section 26 A was a subordinate legislation, an exercise of legislative power, and that therefore the courts need to exercise judicial restraint. The Hon'ble Justices demurred: "This court is of opinion that there is no *per se* bar to reviewing regulatory provisions, even if they are made in the exercise of subordinate legislative power. Such rules or regulations do not *per se* carry a threshold of immunity greater than what any other instrument, either statutory or non-statutory would. The relevant public law standards applicable would be no different, to adjudge their validity." (1: Para 91)

Among the reasons for rejecting the claim of immunity from judicial scrutiny of the impugned notification under Section 26A is that the notification smacked of being manifestly unreasonable, a line of thinking bolstered by references to case law[5] like *Shri Sitaram Sugar Mills Company v Union of India* (1990) 3 SCC 223:

> *… A repository of power acts ultra vires either when he acts in excess of his power in the narrow sense or when he abuses his power by acting in bad faith or for an inadmissible purpose or on irrelevant grounds or without regard to relevant considerations or with gross unreasonableness*.

The impugned notification would be inadmissible because of its gross unreasonableness and bad faith if one considers the disastrous public health impact on women giving birth that it would have had, an irrefutable fact that the discourse of the Union of India repeatedly sought to elide despite advice to the contrary of its own committees and experts. The learned judges cite *Cellular Operators Association v Telecom Regulatory Authority of India* (2016) 7 SCC 703, wherein the Supreme Court ruled that a subordinate regulatory legislation, can be set aside in judicial review, if it shows no rationale or is arbitrary. On both counts the impugned notification is guilty. A third criterion spelt out in *Cellular Operators Association* is whether the subordinate legislative measure is an unreasonable restriction. All change in Government policy "must be in conformity with Wednesbury reasonableness and free from arbitrariness, irrationality, bias and malice."[6]

A major part of the order from Para 98 (1: p 66 of 100) onwards, the Hon'ble Court has taken care to justify, as it were for future legal scrutiny by higher courts, to explain the circumstances in which it would exercise its powers of judicial review, that is when the legality of a subordinate legislation such as the impugned notification involves arbitrariness and infringement of rights. Whether the infringement is excessive or not is for the Courts to decide. (1: para 131):

> *The judicial review standard to be applied when a measure is attacked for arbitrariness is that of Wednesbury reasonableness*.[7] (1: Para 132)
>
> *If an action taken by any authority is contrary to law, improper, irrational or otherwise unreasonable, a court of law can interfere with such action by exercising power of judicial review. One of such modes of exercising power, known to law is the "doctrine of proportionality*.[8]

The judgment sweeps, in masterly fashion, through a welter of details, some of which we have already mentioned above — and much of which we have, regrettably, to skip for reasons of space — leading up to the impugned notification and shows how it suffers from arbitrariness, impropriety, irrationality and is otherwise unreasonable and hence deserves to be rejected.

Lack of balance

Although reluctant to do a "merits review" as part of a judicial review of a notification claimed to be a subordinate legislation, if we go by the above discussion, the Hon'ble Court consciously seems to have crossed the lines; and pronounced its opinion on the impugned notification considering the crucial public

interests involved, above all the public interest of women and preventing their needless deaths due to post-partum haemorrhage. In the context of drawing and crossing lines, we find their Lordships inter alia quoting Oliver W Holmes:

> *All distinctions of law -- even Constitutional law are in the ultimate analyses, "matters of degree". At what line the 'white' fades into the 'black' is essentially a legislatively perceived demarcation*.[9]

In tragic contrast, the learned judges observe in their final order that the

> *…predominant consideration which runs like a common thread through the government's decision making process is that Oxytocin had been misused in the past, resulting in adverse impact on the health of animals. In a case like this assuming the respondents had a good case to conclude Oxytocin was a risk to cattle health nevertheless in the nature of things its therapeutic benefit to humans could not have been overlooked or given less importance*. (1: Para140)

In the end, the Court quashed the notification as both unreasonable and arbitrary as the Union of India did not "adequately weigh" on, inter alia, what banning private manufacture, and restricting manufacture and supply of a life-saving drug, could do to the "increase in maternal fatalities, during childbirth, impairing lives of thousands of innocent young mothers"(1: Para 147), and concluded:

> *…For these reasons, this court is of the opinion that the conclusions recorded by this court – to quote the Supreme Court – do not transgress the arena of permissible judicial review, but rather "enough for us to say that the present case is on the right side of any line that could reasonably be drawn*.[10](italics in original)

We need to celebrate the judgment for its qualities of both heart and mind.

Concluding remarks

Instead of letting the matter rest, the Government has made it a prestige issue. The Union of India has, during February 2019, filed a Special Leave Petition (SLP) in the Supreme Court against the Delhi High Court Order.

In the Delhi High Court, the absence of the several networks of obstetricians and gynaecologists of India to take the lead, legal and otherwise, in defending their view point, in an issue vital for the practice of their vocation, was glaring and disappointing. This was tantamount to ethical failure of such bodies. But they seem to have made amends — better late than never — in the Special Leave Petition in the Supreme Court where the Federation of Obstetricians and Gynaecologists of India (FOGSI) as well as the Indian Medical Association have intervened. During and before the pendency of the matter at the Delhi High Court stage, experts attending the meetings called for by the Government to discuss the scare created by vested interests with regard to oxytocin, refused to subscribe to the need for a ban on private sector production, albeit after a fashion. But in a meeting of all concerned ministries and officials in February 2019, every government bureaucrat and expert has, as it were, decided to present a united front for the Supreme Court. The apparent genuflection of otherwise powerful sections of the Union of India to certain ministerial whims at the risk of jeopardising safe childbirth for women, is a tragedy. KAPL is now being projected as the supremely efficient and confident supplier of oxytocin for the entire country – notwithstanding its poor-quality record which has come to light nor the fact that KAPL was on the chopping block for disinvestment. (13, 14).

We will have to wait and observe the denouement as it unfolds in the coming weeks. For those concerned with the vulnerability of the lives of women in childbirth, it will be sad if the Government privileges, misguidedly, animal well-being over maternal health and safety.

Declaration*: The author is affiliated to All-India Drug Action Network (AIDAN) and LOCOST, Vadodara. AIDAN was a petitioner in the Oxytocin matter before the Delhi High Court and gratefully acknowledges the role of AIDAN legal counsel Colin Gonsalves. An experienced senior community obstetrician/gynaecologist, who does not want to be named, along with AIDAN colleagues Mira Shiva, Malini Aisola and the author were involved in the drafting of the petition and follow up. Anant Phadke and Mira Shiva improved this essay with their comments on an earlier draft. Other acts of omission and commission are those of the author.*

Notes

1 Art 19 (1) (g) says: "All citizens shall have the right to practice any profession, or to carry on any occupation, trade or business."
This right is subject to Art 19 (6):
"Nothing in sub-clause (g) of the said clause shall affect the operation of any existing law in so far as it imposes, or prevent the State from making any law imposing, in the interests of the general public, reasonable restrictions on the exercise of the right conferred by the said sub-clause, and, in particular, nothing in the said clause shall affect the operation of any existing law in so far as it relates to, or prevent the State from making any law relating to:
(i) the professional or technical qualifications necessary for practicing any profession or carrying on any occupation, trade or business, or
(ii) the carrying on by the State, or by a corporation owned or controlled by the State, of any trade, business, industry or service, whether to the exclusion, complete or partial of citizens or otherwise.

2 See: *M/s. Daruka & Co. v. UOI and Ors.* (1973AIR SC 2711)

3 Section 26A in the Drugs and Cosmetics Act, 1940 is about the powers of the Central Government to prohibit manufacture, etc, of drug and cosmetic in public interest:
Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, [regulate, restrict or prohibit] the manufacture, sale or distribution of such drug or cosmetic.]

4 We are not elaborating here on the poverty of the data submitted by the Government in justification of the claim of misuse of Oxytocin by milch cattle owners, the purported smuggling across national borders and the putative raids conducted by the authorities all over the country. But the referenced paragraphs in the judgment convey this to some extent.

5 Other case law cited in this part of the judgment includes: *Khoday*

Distilleries v State of Karnataka 1996 (10) SCC 304; *Cellular Operators Association v Telecom Regulatory Authority of India* (2016) 7 SCC 703.

[6] As held by the Supreme Court in *Shimnit Utsch India (P) Ltd v West Bengal Transport Infrastructure Development Corporation Ltd &Ors*2010 (6) SCC 303.
On Wednesbury reasonableness, see the discussion of Justices Bhat and Chawla in the judgment (1: Paras 96-8). Wednesbury unreasonableness is "A standard of unreasonableness used in assessing an application for judicial review of a public authority's decision. A reasoning or decision is Wednesbury unreasonable (or irrational) if it is so unreasonable that no reasonable person acting reasonably could have made it (*Associated Provincial Picture Houses Ltd v Wednesbury Corporation (1948) 1 KB 223*). The test is a different (and stricter) test than merely showing that the decision was unreasonable." Source: https://uk.practicallaw.thomsonreuters.com/6-200-9152?transitionType=Default&contextData=(sc.Default)&firstPage=true&comp=pluk&bhcp=1

[7] Quoted in *Om Kumar v. Union of India* (2001) 2 SCC 386

[8] *Coimbatore District Central Coop. Bank v. Employees Association* (2007) 4 SCC 669

[9] Requoted from *Shri Kihota Hollohon v. Mr. Zachilhu* AIR 1993 SC 412

[10] As quoted in *Collector of Central Excise, New Delhi v. Ballarpur Industries Ltd. 1989 (4) SCC 566*

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