COMPETITION ACT, 2002 IN COMPARISON WITH THE ANTI-TRUST/COMPETITION LAWS IN USA AND EUROPEAN UNION
Chapter – IV
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Healthcare sector is distinct from other sectors in that there exists an inherent asymmetry of information that renders it difficult for the sector to compete in the manner that other sectors do. For this reason it is often believed that the competition Act may not be applicable to healthcare in the way it is applied in other sectors. However the ultimate purpose of any competition Act is to protect the interest of the consumers and to ensure efficiency and competitiveness in the market. The Competition Act is applicable to healthcare players if they can be considered as undertakings, since hospitals, health professionals, health insurers, pharmaceutical firms, pharmacists, etc. perform economic activities. Thus they can be considered to be undertakings and hence are subject to competition rules. Even in countries where there is little competition among the healthcare players due to excessive regulation, a hospital entering into an agreement with another hospital or pharmaceutical firm would have to comply with the competition Act. Healthcare costs in general, and the price and availability of medicines in particular, are deeply implicated in the poor quality of life of millions of Indians.

In 2011, according to the latest available data, 69% of total health expenditure in India was financed by private sources, of which “out of pocket” (OOP) expenditure by households comprised 86%. The seriousness of the problem goes beyond poverty as conventionally measured. All these calculations are based on households’ reported spending on healthcare, which could have diverted their purchasing power from other important expenditures, such as nutrition and education, which would impair the future earning ability of their members. If they sell productive assets or go into debt to finance healthcare expenses, this too could have a long-term impact on their spending. To the extent that they could not afford treatment, their earning ability would be compromised by premature mortality as well as avoidable morbidity, resulting in workdays lost and

141 Diego Fornaciari; International journal of Environmental research and public health(2009)
142 http://apps.who.int/nha/database viewed 25 April 2013
low productivity at work. Drug pricing and availability is therefore important from both rival perspectives of what constitutes development. From the ‘instrumental’ perspective, it impairs India’s human capital and labour productivity, with adverse consequences for output, competitiveness and growth. The global spend on health-related matters at $6.45 trillion\textsuperscript{143} and rapidly growing fueled by poverty, aging populations, a growing global middle class, chronic obesity in developed and developing societies, communicable and infectious diseases and new expensive therapies.

The competition law in the United States and competition law in the European Union appear to be similar. Article 85 of the Treaty of Rome,\textsuperscript{144} which prohibits agreements that distort competition and, accordingly, agreements that fix prices, is roughly comparable to section 1 of the US Sherman Act\textsuperscript{145}, which prohibits position and seems roughly comparable to section 2 of the Sherman Act, which prohibits monopolization and attempts or combinations to monopolize.

The US and EC competition systems also have common objectives. Both seek to advance the interests of consumers and protect the free flow of goods in a competition economy. Both seek to protect competitors’ access to markets and protect to some extent consumer freedom of choice and seller freedom from coercion.

The respective competitive systems of the two areas have developed, however, out of different histories and different concerns and upon closer examination, significant variations in law, policy and enforcement become apparent.

The US competition policy derives from statutes enacted at different times in history, and therefore the goals of these statutes are not identical. Overall, US antitrust policy is primarily designed to protect consumer welfare (i.e., produce a variety of products at reasonable prices), with modest elements of fairness (right of firms to be free of coercion) and of hostility to vast concentrations of economic power. Through much of its history, US enforcement agencies and courts were not very sensitive to claims of efficiency; they assumed that a robust competitive market would


\textsuperscript{144} This is the treaty establishing the European Economic Community, 25 March 1957, Article 85. The Treaty on European Union (or the Masterchat Treaty), adopted in 1993, did not alter the competition provisions in the Treaty of Rome.

\textsuperscript{145} (US Code, Vol. 15)
automatically be efficient. However, many contemporary commentators believe that efficiency claims are likely to be given more weight in the future.

4.1 ANTI-TRUST LAW IN THE UNITED STATES

The origins of modern competition policy can be traced back to the end of the 19th Century, mainly is a reaction to the formation of trusts in the United States. The events leading to the Sherman Act in the second half of that century, the United States experienced a number of events which resulted in the transformation of manufacturing industries.

Section 1 of the Sherman Act prohibits contracts, combinations and conspiracies which restrain trade and prescribes imprisonment and fines for violators. Section 2 of the Sherman Act prohibits monopolisation, attempts to monopolise and conspiracies to monopolise “any part of the trade or commerce among the several states, or with foreign nations”. The Act carries its own criminal penalties, which might include imprisonment up to three years. During its first decade of life enforcement of the Sherman Act was not very strict. It was not until 1897 that a Supreme Court decision on a trust of 18 railways which fixed the fares for the transport of goods (Trans-Missouri Freight Association) clearly established that price agreements were illegal. Indeed, in this decision and in *Addyston Pipe and Steel*, judges refused arguments aimed at justifying price-fixing, on the grounds that the rates charged were "reasonable" and that price-fixing was as a way to prevent “unhealthy competition”.

146 According to West's Law & Commerce Dictionary (1985), “The trust” was originally a device by which several corporations engaged in the same general line of business might combine for their mutual advantage, in the direction of eliminating destructive competition, controlling the output of their commodity, and regulating and maintaining its price, but at the same time preserving their separate individual existence, and without, any consolidation or merger. This device was the erection of a central committee or board, composed, perhaps, of the presidents or general managers of the different corporations, and the transfer to them of a majority of the stock in each of the corporations, to be held in ‘trust' for the several stockholders so assigning their holdings. These stockholders received in return ‘trust certificates’ showing that they were entitled to receive the dividends on their assigned stock, though the voting power of it had passed to the trustees. This last feature enabled the trustees or committee to elect all the directors of all the corporations, and through them the officers, and thereby to exercise an absolutely controlling influence over the policy and operations of each constituent company, to the end and with the purposes above mentioned”.

147 Note that EU competition law does not allow imposing criminal penalties an anti-trust violations, although certain EU countries’ law do (for instance, Austria, France, Germany, Ireland, whereas the UK is in the process of introducing them)
In *Dr. Miles v. Park & Sons* (1911), the Supreme Court applies the Sherman Act's prohibition of price restrictions to vertical relationships as well. The Court established there that a resale price maintenance clause whereby the manufacturer obliges retailers to sell above a minimum price that it sets, is *per-se* illegal.\(^{148}\)

*Standard Oil Co of New Jersey v. United States*\(^{149}\) is still one of the most famous cases in the history of antitrust. The trust, a creation of Rockefeller had engaged in a series of monopolisation practices - such as localised price cuts deemed to be predatory and a number of acquisitions of minor firms - which were judged against sections 1 and 2 of the Sherman Act.

Another important monopolisation case was *Terminal Railroad case*\(^{150}\), which prohibited several railways that controlled the terminal facilities of the main bridge in the city of St. Louis to discriminate against competitors, and obliged the former to give access to the latter on reasonable terms.

The Sherman Act covers price fixing and market sharing agreements between independent firms, as well as monopolisation practices by individual companies, but not mergers (which were legal unless formed with the intention to monopolise the market using unfair methods of competition). The Clayton Act of 1914 was therefore introduced to extend anti-trust legislation to cover mergers capable of reducing competition, and it was probably the Sherman Act itself that led to a sharp increase in the slumber of mergers in the US.\(^{151}\) The Federal Trade Commission Act also dates from 1914. It created the Federal Trade Commission Act an independent agency that should regulate unfair trade practices, and that shares with the Department of Justice (DOJ), a government agency, the responsibility to enforce anti-trust law in the US at the Federal level (at the State level, Attorneys General can act on behalf of those injured by anti-trust violations).\(^{152}\)

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\(^{148}\) If a business practice is *per se* illegal, no argument can justify it: it is prohibited without exceptions. Under a rule of reason approach, instead, a firm might convince the court that the business practice it adopted does not harm welfare in its particular instance.

\(^{149}\) *Standard Oil Co of New Jersey v. United States* 221 US (1911).

\(^{150}\) *Terminal Railroad case* 1921

\(^{151}\) See Bittlingmayer (1985) for a well documented study.

\(^{152}\) The division of labour between the two agencies is not determined in a precise way. In merger cases, it is typically along sectoral lines that can change over time. However, only the DOJ has enforcement power in criminal cases.
The Clayton Act 1914 has subsequently been amended. The Robinson-Patman Act of 1936 amended its provisions on price discrimination. The focus on efficiency also meant that it was more difficult to win a case against a firm, especially in cases involving vertical restraints and monopolisation. As a consequence, the number of private anti-trust cases filed in US District Courts declined steadily in the 1980s. At the 1977 peak there were 1611 such cases, whereas in 1989 there were only 638.

It is more difficult to identify trends when looking at the very recent past. Probably, apart from some very visible events determined by a change in the government, agencies and court lie somewhere between the interventionism of the 60s and the laisser-faire of the 80s. An important fact is the renewed strength in the fight against cartels, signaled by some prison sentences given in some high-profile international cartel cases, and helped by the introduction of a successful leniency policy that grants amnesty to managers that provide proof of the existence of cartels.

4.2 COMPETITION LAWS IN THE EUROPEAN UNION

The main historical development of competition laws in the European Union, where there are two different levels of jurisdiction: National and supra-national. The latter is more interesting, as most European countries have not had proper competition laws until very recently, and such national laws are to a large extent reproducing the same features as the laws introduced by the Treaty of Rome and its successive modifications.

4.3 COMPETITION LAW IN THE UNITED KINGDOM

One of the first pieces of legislation introduced in the UK to deal with competition matters was the Profiteering Act 1919, whose main concern was to avoid excessive prices after World War I. Towards the end of World War II, the introduction of new competition rules was discussed; with a different motivation. Indeed, unemployment was a major issue then, and the Monopolies and Restrictive Practices (Inquiry and Control) Act 1948 appears to be motivated by the idea that competition in the marketplace would help attain full employment. Since then, a number of changes have been introduced in the UK, until the Competition Act 1998 brought the UK competition law almost in line with the EU’s).

\footnote{In recent years, provisions against price discriminations have rarely been used, though.}
The UK system until the recent major changes was principally based upon the Restrictive Trade Practices Act 1956 (RTPA), which was extended among others by the Resale Prices Act 1964 and by the Monopolies and Mergers Act 1965, and amended by a number of other laws. Rather than adopting a system of prohibitions, under the RTPA agreements had to be registered and they could be challenged in court if found against the public interest. It is debated whether the Act had a real impact on firms' pricing behaviour or not.154

Second, the UK legislation lacked a system of penalties and tools of enforcement. Until the 1998 Reform, unlike their European counterparts, the UK competition authorities were not entitled to search firms' headquarters and seize documents.155 This is clearly a serious limitation when it comes to fighting collusive or predatory practices. Further, competition authorities could not impose fines on firms which had been found engaging in practices against the public interest. Penalties could be given only to recidivists: only if a firm had been the publishing sector found guilty by a court of breaching an order of the Secretary of State and was later caught breaching this court order, could penalties be given, for “contempt of court” (a serious offence). It does not surprise then, that people have been wondering about the effectiveness of the UK competition system in deterring anti-competitive agreements.156

It is important to notice that this concept of welfare completely overlooks the issue of income distribution among consumers and producers. This is not because economists think it is an irrelevant issue, but rather because it is a different issue. The welfare measure is a summarizing measure of how efficient a given industry is as a whole and does not address the question of how equal or unequal income is distributed, which can be dealt with by other measures. Note also that the rationale for not

155 The Director General of the OFT could only ask a company for information if there was suspicion of a restrictive agreement, as well as apply to the courts to have cross-examinations on oath. See Whish (2001)
156 Other critiques have been made about the quality and variability of the decisions taken. For instance, both Utton (2000) and Symcouidis (1998) mention contradictory judgments (which, incidentally, have also the effect of not giving firms legal certainty about the actions they should take) as well as (early) decisions which are today hard to understand. I found particularly curious two arguments made by the court in two separate cases. The first that a cartel might benefit consumers because it would save them time wasted in shopping, around: the second that a cartel reduces uncertainty and therefore the return on capital required by firms in the industry, ultimately lowering prices. See Symeonidis (1998:58 and footnote 3) and Utton (2000:279).
considering distributional issues is that in principle it is possible to operate redistribution schemes such that consumers and producers are both either better off or worse off. Imagine for instance a situation where, as a result of a change in the economy, welfare increases as the net effect of an increase in consumer surplus and a decrease in producer surplus. In theory, it is possible to redistribute gains from consumers to producers in such a way that both groups are at least as well off as they were before the changes took place.

Finally, the concept of welfare should not only be interpreted in a static sense but also in its dynamic component. In other words, future welfare matters as well as current welfare. In the US, both the courts and the anti-trust agencies seem to tend for a consumer welfare standard too, at least as far as mergers are concerned. The most famous instance is given by antitrust laws introduced in the US at the end of the 19th Century, which were initiated from the complaints of farmers and small firms against the large trusts, but this motivation probably lies behind the restrictions to discriminatory practices introduced by many pieces of legislation. It makes sense that the competition authorities do not use their scarce resources to monitor agreements and mergers which involve smaller firms, but there is little rationale behind a systematic use of competition policy.

The main objectives of competition policy as enforced by the EC are most probably economic efficiency and European market integration:

The first objective of Competition policy is the maintenance of competitive markets. Competition policy serves as a tall instrument to encourage industrial efficiency, the optimal allocation of resources, technical progress and the flexibility to adjust to a (hanging environment. In order for the Community to be competitive on worldwide markets, it needs a competitive home market. Thus, the Community’s competition policy has always taken a very strong line against price-fixing, market sharing cartels, abuses of dominant positions, and anti-competitive mergers. It has also prohibited unjustified state-granted monopoly rights and state aid measures which do not ensure the long-term viability of firms but distort competition by keeping them artificially in business. The second is the single market objective.
All internal market is an essential condition for the development of an efficient and competitive industry. The Commission has used its competition policy as an active tool to prevent, [erecting private barriers to trade], prohibiting, and filling heavily the parties to, two main types of agreement: distribution and licensing agreements that prevent parallel trade between Member States, and agreements between competitors to keep out of one another’s “territories.” (European Commission, 2000:6)

Although in most circumstances practices that decrease total welfare also decrease consumer welfare and vice versa (this being the case for cartels, for instance), this is not always necessarily the case. For instance, perfect price discrimination by a monopolist (a situation where each consumer is made to pay exactly its willingness to pay) maximises welfare to the detriment of consumers or, more important since perfect price discrimination belongs to the theoretical realm only, but perhaps not a very frequent case either, a merger that allows the merging firms to decrease significantly their fixed costs might increase total welfare (due to larger profits) while increasing prices and thus decreasing consumer welfare.

Consumer v. total welfare standard in different jurisdictions It is difficult to say whether competition authorities and courts favour in practice a consumer welfare or a total welfare objective. The provision indicates that consumer welfare is among the ultimate objectives of competition law. Competition laws might also incorporate objectives such as fairness and equity, forcing firms to behave in a certain way both with respect to customers and to rivals. A number of public policy considerations often affect competition laws and their enforcement. Indeed, the brief historical account above shows that often competition authorities and courts adopt weaker stances on competition issues than economic considerations alone would have suggested, due to social, political, or strategic reasons. Competition rules have sometimes been relaxed to smooth social tensions.

157 But the Guidelines on Vertical Bestraints, at praa. 7, stae : “The protection of competition is the primary objective of EC competition policy, as this enhances consumer welfare and creates an efficient allocation of resources”. 

158 Several competition lrnvs refer to terms sorb as “fairness” full unfair. Definitions of such concepts are (understandably) rare, and their Ilse is left, to the discretion of competition authorities and courts.
4.4 SHERMAN ACT, 1890

Sherman Act declared illegal all contracts, combinations or conspiracies in restraint of trade or commerce among the states or territories or with foreign nations. The basic requirement is that there should be an agreement or mutual commitment to engage in a common course of anticompetitive conduct. A person is not guilty of monopolization unless he has monopoly power i.e. power to control prices and exclude competition. Therefore offence of monopolization requires monopoly power and intention to monopolize, but there is no monopolization if the defendant’s monopoly power grows as a consequence of superior product, business acumen or historical accident. The competition act has included monopolization but it has not included conspiracy to monopolize. Sherman Act proscribes even attempt to monopolize.\(^{159}\) Competition Act has included the term association of price i.e. price fixing but it hasn’t elaborated the vertical and the horizontal price fixing. If a manufacturer, by using his dominant position, fixes the price with retailer then it is vertical price fixing but if manufacturer fixes price with other manufacturer then it is horizontal price fixing. Vertical price fixing is also knows as price maintenance e.g. Agreement between a film distributor and exhibitor is illegal. A patentee cannot control its resale price through price maintenance agreements. Generally prices are fixed when they are agreed upon. Section 1 of Sherman Act also mentions that dissemination or exchange of price information does not itself establish a violation of section 1 rather price information coupled with criminal intent to fix the price violates section 1 of Sherman act. However a combination or conspiracy within section 1 is established where an agreement exists between competitors to furnish price information upon request.

Competition Act, 2002 has not elaborated the various sorts of tying agreement. It has only defined tie-in agreements as "tie-in arrangement" includes any agreement requiring a purchaser of goods, as a condition of such purchase, to purchase some other goods.\(^{160}\) But in the Sherman Act it has been very well explained. Sherman Act defines Tying Agreements as an agreement by a party to

\(^{159}\) www.corporate.findlaw.com established by evidence of unfair tactics on part of defendant, is required. To establish conspiracy to monopolize three basic things are to be proved: proof of conspiracy, specific intent to monopolize, An overt act in furtherance of conspiracy and there is no need to establish the market power

\(^{160}\) Refer to explanation section 3, Competition Act, 2002
sell one product but only on the condition that the buyer also purchase a different product or agree that he will not buy that product from another supplier. Tying agreements are not illegal per se. An illegal tying agreement takes place when a seller requires a buyer to purchase another, less desired or cheaper product, in addition to the desired product, so that the competition in the tied product would be lessened. Sherman act also pointed out that there should be separateness of products which are tied because if the products are identical and market is same then there is no unlawful tying agreement.

Sherman Act has a special category under refusal to deal called as Group Boycott. Under the Competition Act, 2002 refusal to deal is defined in section 3(4)(d) as "refusal to deal" includes any agreement which restricts, or is likely to restrict, by any method the persons or classes of persons to whom goods are sold or from whom goods are bought. However Sherman Act has explained various conditions of Group Boycott. In case of Horizontal restraints per se rule is applicable but in case of Vertical restraints majority court view is that per se rule is not applicable. There are many sorts of Group Boycott:

- Group Boycott of competitor i.e. joint effort by a firm with dominant market position to disadvantage competitors violates section 1 of Sherman Act.
- An agreement among competitors to stop selling to certain customers is illegal.
- Boycott by physicians, doctors, advocates of a particular customer is unlawful.
- Customer boycott of supplier may or may not, on the basis of circumstances, violate Sherman Act. After the Sherman Act to supplement the Sherman Act there was another act enacted in 1914 named as Federal Antitrust Laws: Clayton Act.

Competition Act, 2002 has not given any place to intention or motive whereas both Sherman Act and Clayton Act has mentioned about the intention of the parties. As per Sherman Act good intentions of parties is no defence to a charge of

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161 The Competition Act, 2002
162 www.justice.gov.
violating the act and thus will not validate an otherwise anticompetitive practice.\textsuperscript{163} Similarly according to Clayton Act it is not required to show that lessen ing of competition or a monopoly was intended.

4.5 THE FAIR TRADING ACT, 1973

This act was passed in England with a view to provide an environment for free competition. This act basically focused on the restriction of monopoly. There is monopoly when a person or group of persons to secure the sole exercise of any known trade throughout the country. However there are certain monopolies authorized by the statute e.g. Post office with respect to carrying of letters. If there is an agreement which gives control of trade to an individual or group of individuals then it creates a monopoly calculated to enhance prices to an unreasonable extent. It is no monopoly if the control is lawfully obtained by particular persons on particular places or kinds of articles for which a substitute is available.

4.6 THE COMPETITION ACT, 1998

The competition Act of 1998 repealed the Fair Trading Act, 1973. The Act deals prohibitions which prohibits the agreements which fix prices, control production, share market or sources of supply, apply dissimilar conditions to equivalent transactions and make the conclusion of contracts subject to acceptance by other parties of supplementary obligations which by nature of commercial usage have no connection with the subject of such contracts. All such agreements are unlawful.\textsuperscript{164} The concept of privileged communication as provided under Section 30 of the U.K Competition Act is also not included in the Indian Competition Act. This non inclusion can affect the right of the undertakings or legal or natural persons who are undergoing investigation.

The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to

\begin{footnotesize}
\textsuperscript{163} www.cci.gov.in  \\
\textsuperscript{164} www.legislation.gov.uk
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exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts.

Competition Law is a complex mixture of a country's law, economics and administrative action intended to favour competition in the economy. Since competition is seen as critical to economic development, competition law seeks to protect this competitiveness in the economy. The underlying theory behind competition law is the positive effect of competition in an economy's market, acting as a safeguard against misuse of economic power. The link between competition law and economic development emphasized over and over again seems rather undeniable and the need for competition law seems like the order of the day. The operation of competition law by prevention of anti-competitive agreements, prohibiting abuse of dominant position by firms and regulation of combinations which might adversely affect competition in the economy, thus seems crucial for India. It is therefore keeping that in mind that the Indian Parliament enacted the Competition Act, 2002. The preamble and the statement of objects and reasons of the Act, also evidence that the broad economic development objectives were a consideration to adopting the Act. Even though the Indian competition law is modelled along the lines of EC law, the Commission is in no way bound to interpret similar provisions in the Indian law in the manner interpreted under the EC law. The Commission on the other hand is bound by the Preamble of the Act to interpret it in a fashion that promotes economic development of the country. This is because the conditions that exist in India are remarkably different than those that exist in the EC and to come to the level where there can be talk of similar interpretation of laws in the two jurisdictions, similar development level would necessarily be a condition precedent. A few amendments that could be added to Competition Act can be as follows:

- Abbreviated rule of reason can be developed especially with regard to cartel cases
- Outer limit of 210 days is given to the CCI under the CA 2002. However the CCI aims at clearing at notices within 180 days. This may lead to unnecessary delays and backlogs.
- Threshold limits for triggering CA are very high especially with regard to a country like India where small industries are prevalent. Hence, it should be taken into consideration that there might be many small enterprises entering
into mergers which may have AAEC but may not trigger the combination regulations under section 5.

- Leniency provisions have been prevalent in India since the beginning of the act but there has been no instance of anyone coming to claim them. The penalties under the act should be hiked in this case so that a deterrent effect is created and leniency provisions are made attractive.

While the basic principles of competition law remain the same the objectives or the results cannot be the same for all jurisdictions. In essence, a progressive realisation of competition policy goals would be the answer to an effective competition law regime in developing countries. While the implementation of competition law even at the early stages of economic development is not bad per se its blind implementation following the path of the developed countries can kill its very objectives. Thus, competition law is a complex creation of law-makers which the Indian Government and the Competition Commission should take time to understand in light of the special needs and requirements of the Indian economy and implement it accordingly.

For example, in the United States, the responsibility for enforcement of competition law lies with two agencies, the United States Department of Justice (DOJ) and the United States FTC. While the DOJ enforces only competition law, the FTC enforces both competition law and the consumer protection laws through Section 5 of the Federal Trade Commission Act, which prohibits both unfair methods of competition and unfair or deceptive acts and practices. Though the FTC was set up in 1914 under the Federal Trade Commission Act, the responsibility for consumer protection was added subsequently in 1938. The FTC has a Bureau of Competition and a separate Bureau of Consumer Protection. Its regional ices originally handled both competition and consumer protection cases but over time most regional offices have come to specialize entirely in consumer protection matters with competition cases being only a small part of their agenda. Waller has observed that, though the FTC has a dual responsibility, it is organized in a way that tends to emphasize the separateness of the two fields rather than their common elements\(^\text{165}\).

In the UK, the OF and in Australia the Australian Competition and Consumer Commission (ACCC) have responsibility for enforcement of both the laws. In India, the MRTPC has responsibility against both anti-competitive practices (“restrictive trade practices”) and anti-consumer practices (“unfair trade practices”) both of which are prohibited under the Monopolistic and Restrictive Trade Practices Act, 1969. In fact, although the MRTP Act was enacted in 1969, the provisions against unfair trade practices were added only several years later in 1984. Since then the unfair trade practices have tended to account for the larger number of cases before the Commission, to that extent distracting it from restrictive trade practices. However; given the seriousness of the issues of consumer protection, India enacted a dedicated consumer protection law, the Consumer Protection Act, 1986. Under this Act a separate mechanism altogether was set up for redressal of consumer disputes. This mechanism consists of District Forums in each district of the country, State Commissions in each state of the country and Kati-o-r al Commission at the apex level. The jurisdiction for hearing consumer disputes has been divided between the three levels of redressal agencies according to the value of the goods or services and compensation claimed, if any, the bigger cases going to the higher-level agencies. The State-level Commissions also hear appeals against the orders of the District Forums and the National Commission hears the appeals against the orders of the State Commissions. Appeals against the orders of the National Commission are heard by the Supreme Court. This extensive machinery, having a network spread all over the country was found to be necessary in view of the large size and population of the country and to provide easy access to the redressal forums for individual consumers and consumer organizations. The Supreme Court of India has observed that the regulation is a milestone in the history of socio-economic regulation and is directed towards achieving public benefit\textsuperscript{166}. In case of competition-related cases it is neither necessary nor possible to replicate a mechanism of the size and reach.

4.7 ANTI-TRUST GOALS IN U.S.A.

Beginning in the late 1970’s, the Courts and Agencies began to adopt the theories of a group of University of Chicago academics, who taught that the only

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\textsuperscript{166} Lucknow Development Authority v M.K. Gupta, (1994) 1 SCC 243.
The legitimate goal of antitrust laws was to promote consumer welfare.\textsuperscript{167} It was held in the case \textit{Broadcom Corp. v. Qualcomm Inc.}\textsuperscript{168} that the primary goal of antitrust law is to maximize consumer welfare by promoting competition among firms. Further, in the case \textit{LAPD v. Gen. Elec. Corp.}\textsuperscript{169} the United States Court of Appeals observed that the antitrust law is designed to protect consumers from the higher prices and society from the reduction in allocate efficiency, which occurs when firms with market power curtail output. The International Competition Network (ICN) recently completed three surveys of its member competition authorities to identify their countries’ antitrust objectives. The third survey, conducted in 2011, explored fifty-seven countries’ conception and application of one often cited goal, promoting consumer welfare.\textsuperscript{170} However, most of the countries considered consumer welfare as a ‘natural result of enforcement activities but not necessarily an underlying goal.\textsuperscript{171}

Moreover, the Harvard scholars opposed market concentration, even when it might lower costs and prices, thereby benefitting consumers.\textsuperscript{172} Harvard scholarship convinced many judges to presume the illegality of any conduct by firms with market power, regardless of its effect on consumers. Judge Hand’s decision in the case \textit{United States v. Aluminum Co. of America}\textsuperscript{173} penalized Alcoa simply for engaging in aggressive competition that benefitted consumers. The Harvard School approach had a similar effect in deterring consumer friendly mergers. In 1963, the Government persuaded the Supreme Court to preclude a merger between two banks in the Philadelphia area that together held only thirty percent of the relevant market. The Court deemed irrelevant the defendants’ arguments that the merger might have enhanced their ability to provide better services to their Philadelphia customers.\textsuperscript{174} The Supreme Court’s decision 1999 in \textit{California Dental}\textsuperscript{175} holds the promise for healing the divide between the Harvard School and the Chicago School. By adopting the variety based approach proposed in

\textsuperscript{168} Broadcom Corp. v. Qualcomm Inc 2008 WL 66932.
\textsuperscript{170} 2011 ICN SURVEY.
\textsuperscript{171} Maurice E. Stucke, Reconsidering Antitrust Goals at Pg. 571
\textsuperscript{172} 75 HARV. L. REV. 655, 663-73(1962).
\textsuperscript{173} United States v. Aluminum Co. of America 148 F.2d 416 (1945)
\textsuperscript{175} California Dental Association v. FTC, 119 S. Ct. 1604 (1999)
that case, the courts and agencies can retain both the clarity of the Harvard School and the economic sophistication of the Chicago school. This approach will clarify the standards of competition for American business, insuring that firms avoid contact harmful to consumers and pursue conduct with the potential to promote consumer welfare.

4.8 EU COMPETITION POLICY:

The European Commission competition regime is closer to the German model where public interest considerations are imperceptibly taken into account than the US model that is more centred on the consumer welfare notion. As Goyder observed, EC competition policy as such is generally driven by economic considerations: where economic goals coincide with consumer interests then a certain consumer protection function will be performed by competition rules. 176 Consumer interest considerations as such are not traditionally a focus of EC competition law, with the exception of Article 82(b) that speaks of practices ‘to the prejudice of consumers’ that has at times been used to guarantee consumer choice as in Magill. 177 EC competition law strives to achieve a multitude of goals. It is not solely designed and applied to achieve the pure competition goal of consumer well being, but it has a multifarious mission that includes the application of ‘extra-competition policies’.

The former Competition Commissioner Brittan’s protestations that ‘for competition policy the interests of the consumer are paramount, protection of consumers per se remains the goal achieved by coincidence rather than through positive action as consumers are assumed to be the ultimate indirect beneficiaries of this policy and of the single market that competition law strives to maintain. Stuyck notes that the consumer is not specifically and technically speaking the beneficiary of the EC competition rules; these rules aim at guaranteeing workable competition rather than at the protection of individual freedom but the enforcement ultimately serves consumer interest, directly, as by prohibiting abuses of monopoly power in inter alia consumer markets, and indirectly by safeguarding a certain level of effective competition. So in so far as the competition rules ensure a fair choice at a fair price of goods, or services of a good quality, they are indirectly promoting consumer interests in the market

economy. However, the Commission has recently undertaken a number of reforms to integrate consumer concerns more closely into its policy-making. For example, the Commission has appointed a consumer liaison officer charged with canvassing consumer opinion on individual competition cases and it has for the first time explicitly stated that the overall goal of its competition policy is to benefit consumers. Moreover, Neelie Kroes, the Commissioner for Competition, stated in her address at Strasbourg, that ‘defending consumers’ lies at the heart of the Commission’s competition policy. The statement reflected the importance of competition policy to consumers, and the importance of consumer welfare when implementing competition policy. Importantly, competition law and policy focus on protecting competition and the competitive process not competitors. Thus, a provider who is put out of business through the ordinary operation of market forces does not have a cause of action under the antitrust laws, no matter how sincerely he believes that his goods and services were superior to that available elsewhere or that his customers were misguided in purchasing from his more successful competitors. Such matters are left to the impersonal workings of the marketplace and not the second-guessing of judges and juries.

Policy analysts who dislike the role of market forces in health care frequently argue that some or all of these consequences are socially undesirable. Competition law and policy proceed from a different premise: not whether the outcomes that result from the operation of an efficient market accord with a particular definition of optimal social policy, but whether the competitive process has been interfered with. This determination is made based on quantitative economic analysis of consumer welfare in the specific product and geographic market at issue. Indeed, the argument that competitive markets result in “undesirable” results is routinely rejected out of hand by courts deciding competition cases. Competition law is cast in expansive terms, and the judiciary has had considerable freedom to elaborate its own understanding of the broad statutory language enacted by Congress. For example, Section 1 of the Sherman Act declares unlawful “every contract, combination…or conspiracy, in restraint of trade.” This sweeping language technically invalidates every contract for goods and services in the United States, since all contracts restrain trade. Not surprisingly, the

178 Eugene Buttigieg, id at Pg 65.
179 Alasdair Murray, Consumers and EU Competition Policy
181 Section 4(1), Competition Act, 2002.
Supreme Court has interpreted Section 1 to prohibit only unreasonable restraints of trade. The other antitrust statutes are similarly broad. Section 2 of the Sherman Act prohibits “monopolization” and “attempted monopolization.” Section 7 of the Clayton Act condemns mergers and acquisitions where the effect “may be substantially to lessen competition, or to tend to create a monopoly.” Section 5 of the Federal Trade Commission Act prohibits “unfair methods of competition” and “unfair or deceptive acts or practices in commerce.”

4.9 ANTITRUST ENFORCEMENT.

The U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) are the primary antitrust enforcement authorities, although state attorneys general can also bring suit. The criminal provisions of the Sherman Act, like all federal criminal laws, are enforced solely by the DOJ. The civil provisions of the Sherman and Clayton Acts also authorize suits by private parties, who can receive treble damages if successful. The FTC Act is enforced by the FTC, both administratively and through the courts. The FTC can also pursue violations of the Sherman and Clayton Acts, either directly or by declaring the conduct an “unfair method of competition.” Similar patterns prevail on the consumer protection side. Since the early 1990s the DOJ and FTC have issued joint statements of antitrust enforcement policy for health care. The statements specify various “safety zones” (circumstances that will not provoke enforcement actions) for hospital mergers, hospital and physician joint ventures, physicians’ provision of information to purchasers, multiprovider networks, and providers’ joint purchasing arrangements. Reflecting its development through selective enforcement and adjudication rather than legislation and regulatory rule making, Competition Law is quite flexible. Different factors are relevant depending on the geographic area, product, and type of conduct at issue. In all antitrust cases, however, the touchstone is whether “market power” is being (or likely to be) exercised. If so, prices are likely to be maintained above competitive levels, and competition among other relevant dimensions (such as quality, service, and innovation) is likely to be lessened. Similarly, in consumer protection cases, the question is whether “unfair” or “deceptive” methods of

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183 See Section 4, Explanation, Competition Act, 2002.
competition are being used. If they are, there is reason to believe that prices do not reflect the quality of the goods and services being purchased.

Competition Law does have limits. Congress can exempt entire industries from the ambit of the antitrust laws, as it did with important aspects of insurance in the McCarran-Ferguson Act.\textsuperscript{185} Congress can also immunize particular activities, as it did with peer review conducted pursuant to the Health Care Quality Improvement Act of 1986.\textsuperscript{186} Similarly, the state action doctrine allows state governments to regulate the marketplace without running afoul of federal antitrust law. To qualify for state action immunity, the state must clearly articulate its purpose to supplant competition and must actively supervise the resulting regime.\textsuperscript{187} State action immunity also extends to private parties acting pursuant to the state mandate. In recent years more than twenty states have enacted laws to protect hospitals, providers, and other health-related entities from antitrust liability.\textsuperscript{188}

4.10 COMPETITION LAW AND HEALTH CARE QUALITY.

Competition law is a bellwether for changes in the way quality has been understood in health care. Conceptually, one can identify three phases in its development. In the first phase, which Goldfarb both heralded and consummated, antitrust law helped break down collective control by the medical profession over the terms of service.\textsuperscript{189} Quality (and its price) would no longer be defined and assessed exclusively by physicians. In the second phase, courts aggressively defended price competition as a legitimate attribute of the health care system, notwithstanding quality-related arguments to the contrary. Courts also cautiously asserted a beneficial effect of competition on quality. As health care became a “big business,” these two phases were necessary to overcome physicians’ resistance to price discounting and corporate

\textsuperscript{185} Price predation has two effects on competition:
  i. It creates entry barriers for prospective competitors (however, its significance is questionable since new firms will not be deterred from entering the market in the recoupment phase.
  ii. It compels existing competitors to exit the market.

\textsuperscript{186} Once barriers are instated and all competitors leave the market, the monopolist is free to increase the price to recoup his losses. Consumers are forced to buy at extremely high prices due to unavailability of alternate options.

\textsuperscript{187} See John Vickers, \textit{Abuse of Market Power}, 115(504) THE ECONOMIC JOURNAL F244 (June, 2005), at p.F248 (Competition Law is concerned with low pricing by dominant firms and not non-dominant firms as the latter are not in a position to exclude others from the market.) Dominance, in India, is determined upon the considerations laid down in Section 19(4) of the Competition Act.

\textsuperscript{188} Herbert Hovenkamp, \textit{Federal Antitrust Policy: The Law Of Competition And Its Practice} (3\textsuperscript{rd} ed., 2005, Thomson/ West), at p. 339

We are now entering a third phase, in which competition law must devise a rational framework that assesses trade-offs between price and quality, fosters innovation, and accommodates concerns (for example, access and trust) that have not historically been given much weight by antitrust enforcers.\(^{191}\)

Throughout much of the twentieth century, health care was marked by physicians’ prerogatives, patients’ deference to physicians, and price-insensitive insurance payments. Each of these elements was explained on the grounds that health care was “special”—that the ordinary rules of market exchange simply would not work. Quality was central to this paradigm. Pre-emption of market forces was justified with the claim that competition would erode physicians’ ethical integrity and result in lower-quality care. Around 1980 this pattern of professional dominance broke down, and competitive forces firmly took root in health care markets. Competition continues to reshape the manner in which medicine is practiced and purchased in America, and law can take considerable credit for this transformation. Indeed, it is only a slight exaggeration to view antitrust law as the engine that powered the emergence of a competitive market in health care.\(^{192}\)

**4.11 IMPROVING ACCESS AND QUALITY BY GENERATING PRICE COMPETITION**

Competition law also engaged quality by addressing price. Policy analysts are used to thinking of a “three-legged stool” of health care resting on separate and distinct components: cost, quality, and access.\(^{193}\) But these legs are interconnected, and lower cost can itself enhance quality. When costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more people are uninsured. The higher the cost of pharmaceuticals, people skip doses or do not fill their prescriptions. Competition law prevents providers from collectively increasing prices above their competitive level or blocking the development of cheaper


In the twenty-eight years since \textit{Goldfarb}, thousands of antitrust suits involving the professions have been filed, most initiated by private parties. Federal and state antitrust agencies were involved in a modest number of litigated cases, but they also exerted influence through formal administrative decisions, consent orders and decrees, and business review letters and advisory opinions. The actual and deterrent effects of these efforts helped to disrupt long-standing patterns of professional dominance and moved health care closer to a competitive model. Even unsuccessful cases had an impact, because market participants could be confident that such conduct would pass antitrust muster in the future. Litigation during this period frequently touched on quality, but quality was seldom a central concern of the parties or the courts. Four themes emerge from close analysis of the case law. First, courts failed to develop specific theories of quality competition in health care, but instead followed standard economic assumptions that quality would improve in tandem with price as the medical profession’s competitive stranglehold was broken. Second, courts began to identify quality with consumers’ preferences as well as professional standards. Because competition law is explicitly based on a model of consumer sovereignty, it encourages consumers to treat health care like any other market, in which they insist on value for money and on the information necessary to make buying decisions. Third, courts started to look beyond physicians to other components of the health care system with the power to define and influence quality through competitive interactions. Fourth, courts began to reassess their attitudes toward quality-oriented self-regulation by the medical profession. While maintaining the position developed in \textit{Goldfarb} and \textit{Indiana Federation} that consumer welfare must ultimately be defined by consumers, competition law is becoming more open to collective action by health professionals so long as it is designed to remedy specific market failures.
4.12 ASSERTING CHOICE AS A COMPETITIVE CONSIDERATION.

Competition law also enhanced quality by maximizing choice in the marketplace. The FTC successfully challenged professional opposition to new forms of health care delivery and financing, such as HMOs, non-physician practitioners, hospital-sponsored clinics, and out-of-town brand-name providers. Among the few victories won by private plaintiffs in staff-privileges litigation were cases involving demonstrably different styles of medical practice that would otherwise be unavailable to patients.

Overall, courts have been much quicker to grasp the competitive importance of assuring consumers a range of health care products and services than they have been to examine the direct effects of providers’ conduct on clinical processes or outcomes. Courts may have felt more comfortable judging dimensions of quality that did not require technical knowledge. But the recognition that consumers’ definitions of quality are broader than those of professionals was itself a critical insight and ensured that consumers would have a fuller range of options than they would have had professional conceptions of quality prevailed.

The flip side of addressing choice in competitive terms is rejecting it as an absolute constraint on marketplace behavior. Courts hearing health care disputes never wavered from the view that antitrust law protects the competitive process, not individual competitors. Two observations flow from this approach. First, competition law helped the health care system distance itself from physicians’ traditional argument that “free choice” by physician of patient and by patient of physician was essential to quality. Instead, courts embraced the idea that choice matters to quality only insofar as consumers value it. This approach is evident in a series of antitrust cases challenging health insurers that contracted selectively with providers. Limiting choice of physicians to enable choice among forms of insurance was considered quality enhancing and thus

198 A situation in which the predator and his rival are differently situated with respect to information critical to decision-making. It is to be noted that the predator is more advantageously positioned, having additional information about production costs, demand conditions and even his own intentions.
pro competitive. Second, by assessing limits on choice as they affect entire markets, rather than individual patients and doctors, competition law stepped away from the dyadic notion of quality that had been the centerpiece of the professional paradigm. This transformation raises the possibility of defining quality in population-based terms in future cases.

A consequence of competition law’s commitment to consumers has been its willingness to accommodate the preferences of health insurers (acting as purchasers of health care services) rather than those of physicians and hospitals (acting as sellers of health care services). In health care, the historical overhang of guild-protective behavior by physicians led courts to look elsewhere for patients’ economic agents, indirectly empowering insurers and employers to articulate competitive preferences for price and quality. Although competition law imposes some restrictions on very large purchasers, the fact that consumer welfare is the touchstone for competitive analysis implies that buyer-initiated changes to the marketplace are generally encouraged. Courts therefore routinely excused major insurers from competitive scrutiny when they contracted selectively with health professionals or imposed onerous contractual requirements on network providers.

Competition law has successfully defended price competition in health care, and courts have made some progress incorporating quality as a competitive dimension. However, the recent rapid conversion of the health care system to market governance places greater demands on competition law. For market processes to result in the appropriate mix of cost, quality, and output, competition law must be proactive. In other words, quality must be fully factored into the competitive mix, allowing consumers to weigh both price and non-price characteristics of health care. Courts have had few guideposts for this endeavor, and health care antitrust cases involving plausible assertions of quality-motivated conduct are accordingly dealt with at a high level of generality.

Developing an effective analytical framework requires reconciling opposite notions of quality. Competition law treats quality as one attribute of a good or service, which must be traded off against price and other attributes, while the medical profession has historically regarded quality as an irreducible minimum standard, to be determined by physicians without reference to cost. As one of us has previously observed, “these conflicting orientations toward quality lead in fundamentally different
directions. The medical professional wants to impose professionally predetermined restrictions on market processes, while the antitrust lawyer strives to free the market from such restrictions, with both groups asserting their positions in the name of quality. The rise and subsequent decline of managed care has not eliminated this conflict, but it has changed the landscape in important ways. First, managed care has sensitized judges to trade-offs between price and quality. Indiana Federation was written as if the primary reason for utilization review was the elimination of waste. A judge familiar with managed care would be more likely to perceive the review procedures as enforcing a price-quality trade-off. Second, the battle between managed care and pharmaceutical companies, played out in the market through pharmacy benefit management and direct-to-consumer drug advertising, has highlighted the importance of non-physicians in the health care system. Third, managed care has increased judicial skepticism regarding the motives of insurance companies that claim to be agents of consumers. Courts may well have become more willing to accept the medical profession (and nonprofit hospitals) as patient representatives. Fourth, the bottom-line orientation of some managed care plans has forced the question of whether a market model is compatible with traditional social objectives in medicine, such as compassion, charity, and trust.

4.13 PRESERVE TECHNOLOGICAL INNOVATION AT THE PATENT-ANTITRUST INTERFACE.

Legal protection of innovation depends on a complex interaction between patent and antitrust law, the former granting a conditional monopoly as an incentive to future inventors, the latter attempting to confine the monopoly narrowly to benefit current consumers. Strategic behavior by patent holders can improperly enlarge the scope of patent protection. Private plaintiffs rarely pursue technology-related antitrust claims because they usually do not meet strict legal requirements regarding standing to sue and antitrust injury. Furthermore, defendants routinely argue that their conduct is shielded by the Noerr-Pennington doctrine, which protects “political action” such as lobbying the patent office or FDA, even if it is engaged in collectively by competitors, and even if it produces anticompetitive effects. Incentives for strategic manipulation of public processes involving patents are particularly intense because the stakes are structured in

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zero-sum fashion: A government decision strengthening one competitor simultaneously weakens all others. These factors make it particularly important for the Dept Of Justice and Federal Trade Commission to make such cases an enforcement priority, as they have done in recent years.200

4.14 FOSTER ORGANIZATIONAL AND INFORMATIONAL IMPROVEMENT.

The International Organization for Migr ation (IOM’s) two reports repeatedly emphasize the adverse quality implications of a fragmented health care delivery system. Competition law can help to address this problem because it encourages providers to integrate clinically and economically at least as long as they do not monopolize a market. Section 1 of the Sherman Act prohibits agreements in restraint of trade, but intra-firm agreements do not violate this provision.201 By forming a single firm, providers can simultaneously enhance quality and insulate themselves from antitrust liability. More generally, direct economic incentives for providers to improve clinical processes are insufficient.202 This “public goods” aspect of health care production suggests that competition policy should look favorably on collective strategies for knowledge generation (figuring out the right thing to do) and dissemination (getting people to do it). The FTC and DOJ have taken a step in this direction by concluding that providers who integrate clinically by developing clinical guidelines or shared information systems may qualify for antitrust protection even though they remain economically independent.203 Health care competition policy has emphasized antitrust, leaving consumer protection enforcers to focus on out-and-out frauds such as cancer cures, miracle weight-loss products, and the like. Although the FTC has been a strong advocate for direct-to-consumer drug advertising, consumer protection in health care remains an unexplored frontier. Informed consent, end-of-life treatment decisions, proxy decision making, and provider report cards present obvious (albeit challenging) targets for a robust consumer protection agenda. Public dollars make up about 45 percent of the $1.3 trillion that the United States spends annually on


202 Section 2(d), Monopolies and Restrictive Trade Practices Act, 1969

203 Explanation to Section 4, The Competition Act, 2002
health care. Public purchasing distorts prices, overbuilds capacity (both physicians and facilities), and skews the development and dissemination of technology. Competition law has largely ignored this reality and indulged the belief that U.S. health care is a private system governed by private competition. In the future, close attention should be paid to the government as both a source of and a remedy for private market failure. For example, competition policy could influence the use of government purchasing power to develop and implement market-oriented solutions to quality problems, such as standardized consumer information. In *FTC v. Butterworth Health Corp.*, the district court allowed the two largest hospitals in Grand Rapids, Michigan, to merge. The court dismissed the concerns of paying customers—managed care organizations—because they purchased care selectively for their own enrollees. Instead, the court looked to the interests of hypothetical consumers, including people who could not afford medical care but nonetheless needed it. It is inconceivable that the merger would have been approved. In addition, courts may misperceive antitrust claims involving hospital mergers as extending beyond economic analysis and calling into question the overall trustworthiness of major community institutions. The goal of a hospital merger case is to prevent the acquisition of market power that will be exploited economically. However, non-profit health facilities are widely presumed to be acting in the public interest, and this expectation is an important part of the reason for according them non-profit status in the first instance. Judges also tend to be receptive to the

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204 Section 19(4), The Competition Act, 2002 The Commission shall, while inquiring whether an enterprise enjoys a dominant position or not under section 4, have due regard to all or any of the following factors, namely: market share of the enterprise;
(a) size and resources of the enterprise;
(b) size and importance of the competitors;
(c) economic power of the enterprise including commercial advantages over competitors;
(d) vertical integration of the enterprises or sale or service network of such enterprises;
(e) dependence of consumers on the enterprise;
(f) monopoly or dominant position whether acquired as a result of any statute or by virtue of being a Government company or a public sector undertaking or otherwise;
(g) entry barriers including barriers such as regulatory barriers, financial risk, high capital cost of entry, marketing entry barriers, technical entry barriers, economies of scale, high cost of substitutable goods or service for consumers;
(h) countervailing buying power;
(i) market structure and size of market;
(j) social obligations and social costs;
(k) relative advantage, by way of the contribution to the economic development, by the enterprise enjoying a dominant position having or likely to have an appreciable adverse effect on competition;
(l) any other factor which the Commission may consider relevant for the inquiry.

205 Femi Alese, *Federal Antitrust And EC Competition Law Analysis* (2008), at p. 342
suggestion that non-profit hospital mergers can help solve the “medical arms race” that seemingly afflicts many communities. From this perspective, competition based on technology is social perversion rather than quality enhancement, and hospitals that reduce such duplication by merging are eliminating waste rather than compromising care.

Competition policy must grapple more explicitly with these beliefs and effects, if only to avoid leaving them to the ad hoc impulses of federal district court judges. For example, the court’s order in *Butterworth* reflected a decidedly nonmarket approach. The court imposed a “Commitment to the Underserved”—a laudable goal, but one fundamentally at odds with the economic underpinnings of traditional antitrust law. At the same time, the court dismissed the importance of price discounts for managed care, blithely assuming that increased revenue to the merged hospital would be spent by the board of trustees on improving quality. Similar instincts may come into play in the recently filed antitrust challenge to the National Residents’ Matching Program, which confronts the court with the possibility that overturning collective restrictions on salaries for medical trainees will increase operating costs and reduce access to services at teaching hospitals. By ensuring a competitive marketplace, competition law and policy prevents a group of providers from preempting “the working of the market by deciding for itself that customers do not need that which they demand.” Needless to say, the medical profession applies a very different set of assumptions where quality is concerned. In an efficient market, consumers’ preferences specify the targets at which providers aim. Some customers are likely to prefer higher-quality care than that currently provided, while other customers are likely to demand lower-quality care, at least as *quality* is defined by the medical profession. The challenge for competition policy in the twenty-first century is to move beyond its traditional focus on price competition and explicitly address the complexities raised by non price competition in all its various manifestations. Health services researchers and health policy analysts have important roles to play in this endeavor.

The government issued a Drugs Price Control Order in 1995 under which the Government has the power to set maximum sales prices of bulk drugs (bulk drugs are pharmaceutical, chemical, biological or plant products including their esters, salts,

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207 *Tetra Pak International SA v Commission of the European Committees* [1996] ECR 1-5951
isomers and other derivatives conforming to the pharmacopeia or standards set by the Drugs and Cosmetics Act). This price setting is done with a view to ensure equitable distribution of such bulk drugs.

The government established the National Pharmaceutical Pricing Authority (NPPA), which has the following objectives:

- Fix and revise prices of bulk drugs and formulations.
- Enforce provisions of the Drugs Price Control Order and monitor the prices of bulk drugs and formulations containing a bulk drug individually or in combination with other drugs.

On 7 December 2012 the Government issued the National Pharmaceuticals Pricing Policy 2012. This has the limited objective to promulgate the principles for pricing of Essential Drugs, as laid down in the National List of Essential Medicines 2011. In May, 2013, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers notified the Drug (Prices Control) Order 2013. This permits the NPPA to regulate prices of 348 essential drugs. India does not have a specific programme under which medicinal products are funded by the state or reimbursed to the patient. However, specific schemes exist to reduce the healthcare costs of patients who are below the poverty line. For instance, private hospitals have been provided incentives (for example land at subsidised rates) for providing free treatment and medicinal products to patients below the poverty line. Further, patients are provided treatment and standard drugs at subsidised rates at government-owned or managed hospitals.

4.15 CLINICAL TRIALS LEGISLATION AND REGULATORY AUTHORITIES

The Drugs and Cosmetics Act is the principal legislation that governs clinical trials in India. More specifically, Schedule Y to the Act was inserted in 2005, which sets out the requirements and guidelines for import and manufacture of new drugs in India.

The Indian Council for Medical Research (ICMR) passed the Ethical Guidelines for Biomedical Research on Human Participants, which include:

- Ethical review procedures.
- General ethical issues.
- Clinical evaluation.
- Epidemiological studies.
• Human genetics and genomics research.
• Transplantation research.
• Assisted reproductive technologies.

In 2002 the Department of Biotechnology passed the Ethical Policies on the Human Genome, Genetic Research and Services, which provides for the regulation and control of genetic studies and genome level research. Under Schedule Y of the Drugs and Cosmetics Act, approval for clinical trials must be obtained from a Licensing Authority and from the respective ethics committee. The Licensing Authority must be informed of the approval of the respective institutional ethics committee and the trial initiated at each respective site only after obtaining such an approval for that site. The clinical trial sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines, as well as with all applicable statutory provisions. The investigators are responsible for the conduct of the trial according to the protocol and the GCP Guidelines.

In all trials, a freely given, informed written consent must be obtained from each study subject. The investigator must provide information about the study verbally as well as through a patient information sheet, in a language that is non-technical and understandable by the study subject. The subject's consent must be obtained in writing using an Informed Consent Form (ICF). Both the patient information sheet and the ICF must be approved by the ethics committee and given to the Licensing Authority. Any changes in the informed consent documents must be approved by the ethics committee and submitted to the Licensing Authority before such changes are implemented. Taking a strict view of regulatory gaps and an increasing incidence of mismanagement and abuse, in October 2013 the Supreme Court stayed about 157 clinical trial programmes pending scrutiny by expert committees set up earlier. The Supreme Court has further mandated that no trials for new drugs will be allowed until the consent of the subject is recorded through an audio-visual medium.\(^\text{208}\) The DCGI made trial registration in the Clinical Trials Registry India (CTRI) mandatory with effect from 15 June 2009. The

\(^{208}\) The draft guidelines formulated by the CDSCO in this regard are available at - www.cdsco.nic.in/writereaddata/Guidance_for_AV%20Recording_09.January.14.pdf
"Responsible Registrant" for a trial is either the principal investigator (PI) or the primary sponsor, to be decided by an agreement between the parties. The primary sponsor is ultimately accountable for ensuring that the trial is properly registered.

The procedural requirements and practices to be adopted while conducting clinical trials are detailed in the Good Clinical Practices Guidelines published by the CDSCO. These guidelines evolved taking into consideration the World Health Organization (WHO), International Conference on Harmonization (ICH), US Food and Drug Administration (USFDA) and European GCP guidelines, as well as the Ethical Guidelines for Biomedical Research on Human Participants issued by the ICMR. These guidelines provide for, for example:

- Procedures for informed consent process.
- Procedures for compensation and confidentiality.
- Special requirements for clinical trials relating to vaccines, contraceptives, surgical devices.

The guidelines must be followed when carrying out all biomedical research in India at all stages of drug development, whether before or subsequent to product registration in India. The ICMR prescribed Ethical Guidelines for Biomedical Research on Human Participants ought to be adhered to while conducting clinical trials. These guidelines focus on the ethical aspects of issues such as, for example, informed consent and compensation for participation. The application for a drug manufacturing licence is made to the relevant State Licensing Authority (Licensing Authority), which scrutinizes the application and forwards it to any of the following three authorities:

- DCGI.
- Joint Drugs Controller of India.
- Deputy Drugs Controller of India.

4.16 CONDITIONS

The following criteria are assessed by the Licensing Authority while granting authorisation for manufacturing medicinal products:

- The qualifications and experience of the expert staff responsible for the manufacture, testing of the drugs and the operations at the manufacturing site.
- The provision of adequate space, plant and equipment for manufacturing operations.
• The provision of adequate arrangements for storage of manufactured drugs.
• For homeopathic drugs, the applicant must ensure that homeopathic drugs are not manufactured simultaneously with drugs pertaining to other systems of medicinal products.

4.17 RESTRICTIONS ON FOREIGN APPLICANTS

Foreign applicants must establish a separate legal entity in India for undertaking manufacturing activities. Such Indian entities are subject to Indian law regulating the manufacture of drugs. The most common legal entity structure used is a subsidiary to the foreign applicant.

The key stages for obtaining authorization for manufacturing of medicinal products are:
• Application for authorization for manufacturing of medicinal products.
• Inspection by an inspector appointed by the government assessing compliance with the conditions for obtaining authorization.
• The inspector submits a report to the concerned authority.
  • The statutory authority, that is, DCGI, Joint Drugs Controller of India or the Deputy Drugs Controller of India, assesses the application.

The manufacturing authorization is valid for a term of five years from the date of issue. For new drugs, it is valid for three years. An application for renewal can be made to the DCGI either during the term of the license or within six months of its expiry. The Licensing Authority has the power to appoint inspectors to make periodic visits to the manufacturing facility to ensure compliance with the conditions on which the manufacturing authorization was granted. In cases of non-compliance with the conditions on which the manufacturing authorization was granted, the DCGI can either suspend or cancel the license or direct the licensee to cease manufacture or sale of medicinal products. An application for the authorization to market new drugs must be made to the Licensing Authority as prescribed under the Drugs and Cosmetics Act and the Drugs and Cosmetics Rules. The substantive legal requirements to obtain a Marketing Authorization are largely the same irrespective of the procedure followed. In assessing whether to grant an Marketing Authorization, the Licensing Authority assesses the medicinal product's:

  Quality, Safety, Efficacy, Risk-benefit balance,
Applicants must also submit the relevant particulars and documents to the Licensing Authority (under Schedule Y of the Drugs and Cosmetics Rules). Applicants must submit a clinical dossier with the relevant information which includes, among other things, the: Results of local clinical trials data. Chemistry, manufacturing and controls (CMC). Quality data.

The norms prescribed for obtaining MA have to be adhered to even post-market entry. If the authorised entity is found to be in contravention of the terms of approval, penal consequences under the Drugs and Cosmetics Act will be imposed. In sum, US and EC competition laws have many similarities, but the substantive centre of gravity of each is unique. EC competition law is derived from the impulse for market integration and is closely connected with the EC principle of free movement of goods and services across member-state lines. It seeks to preserve opportunities for small and middle-sized business, though it is also motivated by concerns for efficient businesses and for customers’ interest.

Moreover, analysis of cases in the European Union had been less technical than in the United States. The Commission and the Court readily presume dominance and increases in dominance without the kind of factual record that might be required in the United States.

The intensity of enforcement is much lower in the European Union than in the United States. Competitor’s complaints and notifications of agreements are the principal triggers of official activity, and minimal resources are devoted to anticartel activity. Resources are devoted to mergers, but few challenges are made. This contrasts with the United States, where anticartel activity is much greater and many more mergers are challenged or subject to spinoff requirements.

Procedurally, the enforcement regimes are quite different. While both are affected by politics, in the United States enforcement is more likely to be influenced by the political philosophy current in the administration rather than direct interference in particular cases. In the European Union, enforcement activity and disposition of cases is more likely to be swayed by ad hoc political influences brought to bear by one of

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209 (see above, Authorisation conditions (www.cdsco.nic.in)).
another member state that perceives an interest in the outcome of the case or the competitive position of EU firms.

There is a perception in both the United States and Europe that EC Article 85 is under enforced with respect to cartels and cartel-like behavior. It is considered under enforced because 1) only the Commission has the right to grant an exemption, and therefore, as a practical matter, all agreement/combination cases must be funneled to it: 2) the Commission has limited resources; and 3) single damages with no significant discovery and the spectre of a double bill for lawyers’ fees provide no incentive for private parties to become effective private attorneys general. There is also a US perception that, beyond cartels, Articles 85 and 86 are both over enforced, deterring firms from taking aggressive action that could serve buyers. However, Europe perceives US antitrust as the captive of big business and Chicago free-market theory and as defaulting in its role to protect against abuses and to limit or regulate power. There is no provision under EC law itself for private antitrust action, but Articles 85 and 86 allow suits in member states for damages or injunctive relief in accordance with whatever procedures and remedies the member-state law provides. Some EU officials and others advocate greater use of private actions.