CHAPTER 3.

EXEMPTIONS TO ANTI-COMPETITIVE AGREEMENTS

3.1 INTRODUCTION

Competition law is applicable to mostly all forms of economic activities and sectors in a country; however, there are certain exceptions to the application of competition law. This means that such activities will be excused from the scrutiny of the competition authorities. The purpose or object behind such exemptions or exceptions may vary from being social, economic or political such as ‘balancing of unequal economic or bargaining power, issues relating to information or transaction costs, reducing risk of uncertainty and addressing demands of a special sector’. Such exemptions do not always reduce the effects of antitrust enforcement since they are backed with certain purpose. There are certain common behaviours and transactions which have been accepted as exemptions by most of the antitrust authorities. Following is a deliberation regarding exemptions under the US, EU and Indian competition law which relate to anti-competitive agreements. This would help understand the legal contours on which competition authorities in these jurisdictions allow certain agreements whereas term the others as restrictive or anti-competitive. From the perspective of healthcare delivery services, it will also assist in identifying areas within the Indian competition law which require to be relooked so that better competition prevails in the market.

3.2 EXEMPTIONS UNDER THE US ANTITRUST LAW

In United States there are certain areas where anti-competitive agreements have been exempted from antitrust scrutiny. These are:

a. Agriculture;

b. Energy;

c. Transportation;

d. Banking and insurance

e. Newspapers;

f. Learned professions and
g. Baseball.¹

Along with the above, the Federal Trade Commission (FTC) and Department of Justice (DOJ) have issued *Antitrust Guidelines for Collaborations among Competitors, 2000.*² This Guideline lays down certain 'safety zones' for agreements or collaborations amongst the competitors. The purpose of the safety zone is to provide a degree of certainty to the participants of 'those situations in which anti-competitive effects are so unlikely that the arrangements are to be lawful without inquiring into particular circumstances.'³ Such Guidelines assist the participant to the collaboration to safeguard the agreement from antitrust risk by understanding the agencies approach towards them.

According to the *Guideline⁴* if the competitor collaboration collective market share accounts to less than twenty percent of each relevant market where competition may be affected then the Agencies (FTC and DOJ) will not challenge the collaboration. However, this safety zone does not apply to agreements that are *per se* illegal or 'that would be challenged without a detailed market analysis or to the competitor collaborations to which a merger analysis is applied'.⁵

The *Guideline* also gives a ‘safety zone’ relating to competitor collaboration in an innovation market. These collaborations will not be challenged when:

Three or more independently controlled research efforts in addition to those of the collaboration possess the required specialized assets or characteristics and the incentive to engage in R&D that is a close substitute for the R&D activity of the collaboration. In determining whether independently controlled R&D efforts are close substitutes, the Agencies consider, among other things, the nature, scope, and magnitude of the R&D efforts; their access to financial support; their access to intellectual property, skilled personnel, or other specialized assets; their timing; and

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¹ Exemption from antitrust laws of agreements covering the telecasting of sports contests and the combining of professional football leagues, (Oct 11, 2017), available at [https://www.law.cornell.edu/uscode/text/15/1291](https://www.law.cornell.edu/uscode/text/15/1291)


³ *Id.*

⁴ *Id.*

⁵ *Id.*
their ability, either acting alone or through others, to successfully commercialize innovations.

These safety zones give much direction and assurance to many R&D agreements entered in different markets. R&D agreements are of immense importance in the healthcare sector to bring in improved techniques and devices which cost less. To have certain guidelines laid down by the competition authorities would help in the long run to improve and sustain competition in any market. These ‘safety zones’ as mentioned above do not apply however in case of an agreement which is per se illegal. In that case the antitrust provisions will apply normally and the agreement will be subject to antitrust scrutiny.

Under the US antitrust law there are no block exemptions or safe harbour provisions which are relevant to the analysis of vertical restraints. This means that all vertical restraints would be subject to antitrust examination. Following lays down in brief the various safety zones which exists under the American antitrust law for various horizontal agreements.

### 3.2.1 SAFETY ZONE IN INTELLECTUAL PROPERTY RIGHTS

The DOJ and FTC have issued *Antitrust Guidelines for the Licensing of Intellectual Property* in January, 2017 replacing the earlier Guidelines of 1995. The new Guidelines lay down antitrust policy of the agencies relating to the licensing of patent, copyright and trade secret law along with know-how. It does not cover the antitrust treatment of trademarks. The requirement of new guidelines was to update IP licensing on account of new legal development.

The 2017 *Guidelines* embody three general principles for the purpose of antitrust analysis, stating that the agencies:

- Apply the same analysis to conduct involving intellectual property as to conduct involving other forms of property, taking into account the specific characteristics of a particular property right;

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• Do not presume that intellectual property creates market power in the antitrust context; and
• Recognize that intellectual property licensing allows businesses to combine complementary factors of production and is generally pro-competitive.

Along with providing the agencies’ approach on the enforcement of intellectual property licensing, the Guidelines also mention a ‘safety zone’. The agencies maintain that because licensing agreements often promote innovation and enhance competition, an antitrust ‘safety zone’ is useful to provide some degree of certainty and thus to encourage such activity. It is not intended to suggest that parties should conform to the safety zone or to discourage parties falling outside the safety zone from adopting restrictions in their licensing arrangements that are reasonably necessary to achieve an efficiency–enhancing integration of economic activity’. The Guidelines also lay down the consideration on which arrangements which fall outside the safety zone are to be analysed.

The Guidelines state:

Absent extraordinary circumstances, the Agencies will not challenge a restraint in an intellectual property licensing arrangement if (1) the restraint is not facially anticompetitive and (2) the licensor and its licensees collectively account for no more than twenty percent of each relevant market significantly affected by the restraint. This ‘safety zone’ does not apply to those transfers of intellectual property rights to which a merger analysis is applied.

Further it clarifies that if on an examination of the effects of competition among technologies or in R&D is required and the market share data is either not accurate or unavailable to significantly represent the effect then the agencies will not challenge a restraint in an intellectual property licensing arrangement in certain circumstances. One, the restraint is not facially anticompetitive and two, there are four or more independently controlled technologies in addition to the technologies controlled by the parties to the licensing arrangement in addition to the technologies controlled by the parties to the licensing arrangement that may substitute for the licensed technology at a comparable cost to the

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9 Id.
10 Id.
11 Id.
user. The Guidelines also explains how to evaluate close substitutes and the factors to consider. Hence, the Guidelines provide an exhaustive set up for handling agreements in IPR which are anti-competitive with factors, safety zones and methods to analyse the arrangements and markets.

3.2.2 SAFETY ZONE IN HEALTH CARE

Understanding the importance of health care industry, the Federal Trade Commission and Department of Justice issued in September, 1993, six policy statements containing ‘safety zones’ for provider conduct that the agencies generally would not challenge under the antitrust laws. These statements reflected prosecutorial standards based on the agencies’ previous advisory opinions, case law, and experience with respect to the covered activities. These policy statements were later updated and expanded in September, 1994, when the agencies issued nine statements of enforcement policy and analytical principles. Seven of the statements contained safety zones, and two statements described the agencies’ analytical process for analyzing certain health care activities. Later in August, 1996, responding to the changes within the US health care market, both DOJ and FTC issued revision to statements eight and nine concerning physician network joint ventures and multi-provider networks. Following are the areas in which the statements were made:

1. Mergers

Mergers of general hospitals are not to be challenged by the agencies except in extraordinary circumstances. The general hospital in this regards means where one hospital has fewer than hundred beds, fewer than forty patients a day and has been in existence for more than five years.

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12 Id.
13 Id.
15 Id.
2. High Tech Joint Ventures

Except in extraordinary circumstances, the Commission will not challenge joint ventures among hospitals to purchase, operate and market high-technology or other expensive medical equipment, that involve only the number of hospitals necessary to support the equipment. If more than the minimum number of hospitals are included in the venture, but the additional hospitals could not support the equipment on their own or through a competing joint venture, the agencies will not challenge the venture. Neither the FTC nor the Justice Department has challenged an integrated joint venture to provide such services.  

3. Joint ventures involving specialised clinical or other expensive healthcare services

Regarding such joint ventures of hospitals to provide specialised clinical or other expensive healthcare services, the statement explains in details the manner in which the agencies will analyse them. The rule of reason analysis would be done in this aspect. The statement does not create any safety zone for such ventures since ‘the agencies believe that they must acquire more expertise in evaluating the cost of, demand for, and potential benefits from such joint ventures before they can articulate a meaningful safety zone. Neither the FTC nor the Justice Department has challenged an integrated joint venture to provide such services.’

4. Information sharing

The statement explains that the Commission will not challenge the collective provisions by health care providers of medical information to help purchasers of their services resolve issues about the mode, quality or efficiency of medical treatment. The FTC hence, would not object to a medical society collecting outcome data from its members about a particular procedure and afterwards providing that information to purchasers. However, this does not protect the provider conduct to coerce compliance with recommendation, and does not cover the collective provision of fee-related information to purchasers.

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16 Id.
5. Information Collection

Under the Statements of Antitrust Enforcement Policy in Health Care\(^1\) an antitrust safety zone is created ‘with respect to collective provision of fee-related information.’ For information to qualify this ‘safety zone’ it must satisfy the following conditions:

1. be managed by a third party;
2. contain information based on data that is more than three months old; and
3. Contain shared data aggregated from at least five providers, of which no individual provider represents more than twenty five percent, and be sufficiently aggregated to prevent identification of prices charged by any individual provider. The sharing of prospective fee related information falls outside the antitrust safety zone, and will be assessed on a case-by case basis, including scrutiny of the nature and extent of communications, the rationale for providing the information, and the nature of the market in which it is provided\(^2\)

Further, with respect to exchange of price and cost information among competing providers which don’t come under the ‘safety zone’, rule of reason analysis will be conducted on them. Therefore, Agencies have focused their primary concern in the Guidelines towards information exchange involving competitively sensitive information – e.g., recent, current and future pricing, cost information, and output information – because such exchanges might facilitate market allocation or price fixing among competitors in the health care providers market. Being a complex industry with multiple sub markets within it, this step by the US antitrust agencies has been effective over the years in identify and curbing anti-competitive agreements amongst associations of physicians.

6. Price Surveys

The Health Care Statement\(^3\) also provides a general guidance from the perspective of antitrust where health care service providers such as hospitals, physician groups participate in written survey of prices for health care services or compensation costs such as salaries or benefits. It acknowledges that such surveys can have significant benefits to health care consumers, providers as well as purchasers when they are conducted keeping appropriate

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\(^1\) US DOJ and FTC, Statements of Antitrust Enforcement Policy in Health Care 1996, supra note 13 at 113

\(^2\) Id.

\(^3\) Id.
safeguards against collusion or any other type of reduction in competition. To satisfy these conditions, the survey must be managed by a legitimate third-party; the data provided by hospitals must be more than three months old; and at least five hospitals must report the data on which each statistic is based. No one hospital’s data can represent more than 25% of the statistic, and the survey results must be sufficiently aggregated to make it impossible to determine the prices or compensation for any particular hospital.

7. Purchasing arrangements

The FTC in the Statement explains that till joint purchase arrangements among healthcare providers do not become monopolistic or indulge in price fixing, it will not challenge the arrangement. To fall within this safety zone, the purchasers made by the health care providers must account for less than 35% of the total market for the purchased items; and for joint purchasing arrangements including direct competitors, the cost of the purchased items must account for less than 35% of the total market for the purchased items, and the cost of the purchased items must account for less than 20% of the total revenues of each purchaser.

8. Physician Network Joint Ventures

In the revised Statement of 1996, FTC has in detail dealt with the physician network JVs. The statement explains that where physicians’ integration through the network is likely to produce significant efficiencies, any agreements on price reasonably necessary to accomplish the venture’s pro-competitive benefits will be analyzed under the rule of reason. The revisions focus on the analysis of networks that fall outside the safety zones, particularly those networks that do not involve the sharing of substantial financial risk by their physician participants.

Further, it states that:
The safety zones for physician network joint ventures (exclusive physician network joint ventures comprised of no more than 20% of the physicians in any specialty in a geographic market who have active hospital staff privileges and who share substantial financial risk; non-exclusive physician network joint ventures comprised of no more

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20 Id.
21 Id.
22 Id.
than 30% of the physicians in each specialty in a geographic market who have active staff privileges and who share substantial financial risk) remain unchanged, but the revised statement identifies additional types of financial risk-sharing arrangements that can qualify a network for the safety zones. The statement adds three hypothetical examples to show how the agencies will apply the antitrust laws to specific situations.23

9. Multi-provider Network

These are ventures among providers to jointly market their services to health benefits plans. Due to them being involved in a large variety of structures and relationships with different types of health care providers, the Statement clearly mentions FTC inability to set out a safety zone for such multi-provider network. These are analysed from the perspective of rule of reason since they are expected to produce ‘efficiencies that benefit consumers, and if any price agreements by the networks are reasonably necessary to realize those efficiencies.’ The revised Statement sets forth four hypothetical examples of how the agencies will apply the antitrust laws to specific situations which involve these networks.24

Another development in the US healthcare industry which has had a significant effect on the antitrust application is the recent enactment of the Patient Protection and Affordable Care Act25. The FTC and DOJ have issued Statement of Antitrust Enforcement Policy Regarding Accountable Care Organisation Participating in the Medicare Shared Saving Program26 under which Accountable Care Organization (ACO) such as group of doctors, hospitals who together volunteer to give good quality care to Medicare27 patients and which participate in Shared Savings Program have been exempted from the mandatory antitrust review. However if they are engaging in collusion or improper exchange of price information or other

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23 FTC, Overview of FTC actions in health care services and product 2017, supra note 15 at 114
24 Id.
27 Medicare is a form of federal health insurance in the United States covering people who are 65 or older, young people with disability and people with end stage renal disease, (July 23, 2017), https://www.medicare.gov/sign-up-change-plans/decide-how-to-get-medicare/whats-medicare/what-is-medicare.html
competitively sensitive information with respect to their sale of competition services outside the ACO, then they will not be given the excuse of this ‘safety zone’.

A regulation within the US healthcare industry which provides targeted exemption to certain insurance activities is the McCarran-Ferguson Act of 1945. It was passed to protect small newly incorporated insurance companies who required data from existing insurance companies to set the premiums. Due to information sharing of such data was illegal under the antitrust law; the Congress passed this Act to create an exemption from antitrust scrutiny. This Act allows insurers to pool historic loss information so that they are better able to project further losses and charge actuarially based prices for their insurance products. The exemption is therefore relating to sharing of information and pricing for insurance premiums. It further allows joint development of policy forms.

the net effect of the limited exemption under McCarran-Ferguson is actually to increase competition by giving small insurers, who otherwise would have too little data to develop actuarially credible (i.e. statistically reliable) rates, the tools to compete with larger insurers who have much more data on which to base rates. The principle is simple: better data produce rates that are more accurate, and rates that are accurate are fairer to consumers. The fact that a larger number of insurers can secure the data they need to compete under McCarran means that consumers are afforded more choices, not fewer.

Under this federal law, the insurers are however, not exempted from state antitrust law. This means that insurers would be liable to antitrust violation if they conspire to fix prices or in any other manner restrict competition. The Act does not apply on claims handling or settlement practices under the insurance business. Over the years this Act has come under severe criticism and many are of the opinion that it should be repelled. It is debated that conditions in the insurance industry especially the health insurance have drastically changed.

28 Federal Trade Commission and Antitrust Division of the Department of Justice, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, supra note 26 at 116


Now the American insurance market is highly concentrated and dominated by few insurers. It was hoped that the State regulations would keep the anti-competitiveness in check; however, this has not been the case. There have been four bills introduced in the US Congress for repealing the Act, these remain pending. In case these bills get passed, they would end special treatment for the insurance industry and bring in transparency with antitrust agencies being able to investigate information exchange collusions on premiums.

Hence, looking at various guidelines issued by the antitrust enforcement agencies in the United States, it can be seen that FTC’s Health Care Division has particular interest in examining the collection, exchange and provision of information, including price information among health care providers. Further both FTC, DOJ have taken significant steps in ensuring better antitrust assessment of certain crucial aspects of the healthcare delivery industry, such as healthcare providers and the information shared by them. In India there is no specific guideline or statements which can serve as a guiding light for the assessment of complaints before the Competition Commission of India which are health care industry related. Further due to the absence of such antitrust guidelines self evaluation by parties to an agreement which may fall under the scrutiny of competition law is also not possible.

### 3.3 Exemptions Under the EU Competition Regime

It is to the peculiarity of the EU competition law that there are certain agreements which benefit from what are known as ‘specific block exemptions’. These exemptions benefit from not being examined under Article 101(1) of TFEU (agreements and collusive practices which are anti-competitive). These ‘block exemptions’ have a time frame mentioned within the guidelines as well i.e. till when they are in effect


Under these ‘block exemptions’, the Commission has notified certain practices which will be considered in accordance with Art 101(1). This makes it easier for the parties to such agreements to carry them out without the process of individual notification. These exemptions also provide ‘desirable legal certainty for firms and their professional advisers’ in entering an agreement and terms incorporated in them. Such agreements cannot be declared invalid by a national court. These exemptions have been made in the area of:

1. Vertical agreements
2. Vertical agreements in the motor vehicle sector
3. Insurance sector
4. Research and Development agreements
5. Specialised agreements
6. Technology transfer agreements
7. Agreements between small and medium sized undertakings in the road and inland waterway sector

36 Id.
8. Consortia between liner shipping\textsuperscript{44}
9. Certain agreements in the air transport sector\textsuperscript{45}

All the above ‘block exemptions’ serve as ‘self-regulatory mechanisms: if the parties of an agreement are careful enough to comply with all the requirements then they can be certain of the agreement’s accordance with EU law’. \textsuperscript{46} Following is a brief discussion on the Regulations which may have an effect on the healthcare delivery services.

### 3.3.1 BLOCK EXEMPTION ON VERTICAL AGREEMENTS

The Regulation issued in the year 2010\textsuperscript{47} defines key terms such as ‘vertical agreements’ and ‘vertical restraints’. Article 2 of the Regulation explains that many vertical agreements do not violate Art 101(1) and ‘no matter how generous and flexible the Regulation is, it will not be necessary to bring the agreement in question within its terms.’ Despite this, number of companies and undertakings take the efforts to satisfy these ‘block exemptions making them a ‘safe haven for many vertical agreements. In case a vertical agreement is not as per the criteria set out in the Regulations, it does not mean that such agreements become automatically void. In such a scenario, its the parties to the agreement who must assess whether the agreement is likely to violate the Regulation. In case it does not then the parties do not have to consider the matter any further , however, if it does fall with the ambit of the prohibition they must evaluate the benefits of this vertical agreement vis-a-vis to restriction on competition . These include:

1. Efficiency gains


\textsuperscript{46} Sandra Amrco Colino, Cartels and Anti-competitive agreements Vol 1, 2012, Ashgate

2. Consumer getting fair share of the resulting benefit
3. Substantial elimination of competition
4. Does the agreement impose any other restraint on competition than necessary for efficiency gain?

In case the vertical agreement in question has fulfilled any of the above, then it justifies individual exemption.

According to this Regulation, in order to be exempted the following must be satisfied:

1. There must be vertical agreements.
2. The market share of each of the parties to the agreement must not exceed thirty percent.
3. There must be no hardcore restrictions in the agreement.\(^{48}\)

There are some agreements which have been said to contain ‘excluded restrictions’ under the vertical agreements block exemptions. In case an agreement contains them then the block exemptions provided will not apply to that specific restriction. However, the rest of the agreement can benefit from the block exemption if it fulfils the above criteria’s if the ‘excluded restriction’ is severable from the entire agreement. These ‘excluded restrictions’\(^ {49}\) are:

1. restricting the buyer from purchasing, or otherwise dealing with, competing products of the purchased products, directly or indirectly (e.g. this will include the situation

\[^{48}\]As per these Regulations, hard core restrictions are those which:

- restrictions on the buyer's ability to determine its own prices (i.e. no minimum or fixed prices can be agreed, although maximum sales prices and recommended prices are usually acceptable);

- territorial and customer restrictions generally, though prohibiting the buyer/distributor from actively seeking customers in a territory or from a customer group that has been reserved for the supplier or another buyer/distributor, is permitted in certain circumstances, as is restricting all sales to end users by a wholesale buyer);

- territorial and customer restrictions on sales within a "selective distribution system", where buyers are chosen on the basis of pre-determined criteria (although a supplier may restrict, amongst others, a distributor in a selective distribution system from selling to other dealers who are not "authorised"); or

- restrictions on sales of components (though buyers may be prohibited from selling the component on to competitors of the supplier, suppliers may not be barred from selling components as spare parts to end-users, repairers or other service providers on the aftermarket of the buyer's product).

\[^{49}\]Article 5 of the Regulations
where the buyer is obliged to buy more than 80% of its total purchases of the product from the supplier) for more than five years (non-compete obligations);

2. restricting the buyer from competing after the termination of the agreement, except where the restriction is limited to one year, is necessary for the protection of know-how and is limited to the same point of sale from which the buyer has operated during the agreement\(^50\); or

3. Restricting members of selective distribution systems from selling particular competing brands.\(^51\)

### 3.3.2 EXEMPTION OF TECHNOLOGY TRANSFER BLOCK EXEMPTION

The European Commission has issued *Technology Transfer Block Exemption Regulation (TTBER) on the application of Art 101(3) of the TFEU*\(^52\). It covers licensing agreements in relation to intellectual property rights (IPR) giving a safe haven for the undertakings participating in that field of business. When the agreement comes within the terms of this block exemption, such IPR related agreements will not be scrutinized by the Commission.

The 2014 Regulation applies to patents, know-how, software copyrights (except reproduction and copying) and combinations of such rights. Along with these the Regulation also applies to assignment of technology rights, provided the licensor retains part of the risk of exploitation. Agreements relating to trademark are not covered. Even multi party agreements fall outside the scope of TTBER. Consequently the TTBER will not apply to 'patent pool' arrangements but the accompanying guidelines set out guidance on when such arrangements would be acceptable.\(^53\)

The application of this Block Exemption Regulation occurs only when there is an IPR and through an agreement its technology transfer is being done for the purpose of production of

\(^{50}\) *Id.*

\(^{51}\) The Vertical Agreements Block Exemption, (July 21, 2017), available at [https://www.out-law.com/page-9148](https://www.out-law.com/page-9148)


\(^{53}\) The Technology Transfer Block Exemption, (Oct 8, 2017), available at [https://www.out-law.com/page-7091](https://www.out-law.com/page-7091)
goods or services. These do not cover research and development agreements as well as supply agreements.

These Regulations are based on three assumptions:\(^{54}\):

i) the European Commission is of the opinion that IP laws and Competition laws share the basic objectives of promoting consumer welfare and an efficient allocation of resources:\(^ {55}\);

ii) the IPR owner must not be unduly restricted of his IPRs so as to allow him to recover sufficient monetary gain, including recovery of sunk costs and

iii) There is no presumption that IPR licensing as such gives rise to competition law concerns.\(^ {56}\)

For a licensing agreement not to be challenged from antitrust perspective, there are two ‘safe harbour’ provided under the TTBER based upon two conditions –

a. The contracting parties do not exceed the market threshold. A collective market share of up to twenty percent of the relevant market in case the parties to the agreement are competitors and if not the market threshold is thirty percent, and

b. The concerned agreement must not include any ‘hardcore restrictions’ mentioned under Art 4 of the Regulation. These restrictions have been divided on the basis of agreements entered between competing undertakings and those which have been entered between non-competing undertakings.

Hence, if either of the above requirement is not met, the agreement will not be exempted under these Regulations and will be subject to an individual assessment under Art 101(1) and (3) of the TFEU. Further Art 5 of the TTBER excludes certain provisions from the block exemptions i.e. these agreements may be harmful to the competition, however if any provision is of such a nature, it does not vitiates the entire agreement as in the case of ‘hardcore restrictions’.

\(^{54}\) TFEU, supra note 34 at 120.

\(^{55}\) Id.

\(^{56}\) Id.
3.3.3 EXEMPTION OF HORIZONTAL AGREEMENTS

The Commission adopted in December 2010 a new Guideline on Horizontal Co-operation\(^{57}\) which takes an ‘effect based’ approach meaning ‘where the companies involved do not enjoy market power, the horizontal cooperation generally do not have anti-competitive consequences’. The Guideline also consists of block exemption regulation on research and development collaboration and specialisation agreements.

i. Research and Development horizontal agreements

Research and development agreements may be of vital importance for a company’s business especially if the company is working in pharmaceutical or medical device industry. Such agreements help bring in innovative products and services to the market. Some companies do their R&D on their own while others choose to collaborate with other companies. EU’s competition policy has a positive attitude towards such R&D agreements being only ‘wary of agreements extending to subsequent joint exploitation of the results of the R&D.

Appraising whether R&D collaboration is caught by the Article 101(1) prohibition involves considering the following preliminary points:\(^{58}\)

a. Is there an agreement between two or more independent undertakings? For example R&D agreements between members of the same group are not caught by Article 101;

b. Is the R&D agreement capable of affecting trade between Members States to an appreciable extend? R&D agreements are more likely to affect inter-State trade if they are concluded between undertakings from different States or if the markets to which they relate extend beyond single Member State; and

c. Does the R&D agreement prevent, restrict or distort competition to an appreciable extend in a relevant market within European Economic Area?

Considering the pro-competitiveness of the R&D contracts, the Commission has adopted certain block exemptions in this aspect. Hence, where an R&D horizontal agreement comes

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\(^{57}\) Id.

under Art 101(1) meeting the criteria, it as be assured of block exemption making it valid. Such agreements which do not meet them will not necessarily be condemned under the EU law. ‘They may still fall outside Art 101(1) altogether, but even if Article 101(1) is applicable they may still be appraised favourably in accordance with the principles of Art 101 and 102. These block exemptions are applicable to R&D agreements which contain provisions relating to:

1. The assignment or licensing of IPRs to one or more parties to carry out the joint research and development;  
2. Paid-for research and development;  
3. Joint exploitation, provided that those provisions do not constitute the primary object of such agreement but are directly related to and necessary for their implantation.  

These exemptions are in place till 31st December 2022.

ii. Specialisation horizontal agreements

Production agreements are agreement between two or more parties who may be competitors, relating to conditions under which they would collaborate for production of goods or provision of services. The *Guideline* defines it as:

1. Joint production agreements in form of a joint venture.
2. Horizontal subcontracting agreements where actual or potential competitors agree to:
   a. Unilateral specialisation agreement is between two parties in the same product market where one party ceases to produce the product and agrees to purchase the product from the other party.  
   b. Reciprocal specialisation agreements- where two or more competitors agree on a reciprocal basis to cease production, fully or partly of certain different products and source them from others. Example When a company x decides to

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59 *Id.*  
60 *Id.*  
61 *Id.*  
63 *Id.*
stop making product A and agrees to purchase it from another company Y who stops producing product B and agrees to purchase it from X.

c. Subcontracting agreements- These are agreements where the contractor entrusts the sub contractor with the production of a product, while the contractor does not at the same time cease or limit its own production\textsuperscript{64} of the product, thereby expanding its overall production.

**Block exemption**

Article 101(1) of the TFEU is not applicable to specialisation agreements which include joint production agreements provided the agreement does not contain any hardcore restrictions of competition such as fixing of price, restricting output or sales and client or market allocation and does not exceed combined market share of twenty percent.

These exemptions also extend to specialisation agreements which relate to either assignment or licensing of intellectual property rights as long as those provisions are not the primary object of such agreements, instead directly related to and necessary for their implementation. Further an exemption is also given where parties accept exclusive purchase or supply obligation or jointly distribute the products they manufacturer under a specialisation or joint production agreement.

Dealing more specifically with the market share:

It is calculated on the basis of the market sales value or, if that data is not available, then estimates based on other reliable market information may be used to establish the market share of the parties. If, after a certain time, the market share exceeds the 20\% threshold but remains below 25\%, the exemption continues to apply for two years. However, if the market share rises over 25\%, the exemption only applies for the following one year\textsuperscript{65}.

From the brief discussion above, it can be gathered that both in the United States and EU there are various types of ‘safety harbour’ or ‘block exemptions’ created by the antitrust authorities to encourage innovation and competition by assuring number of horizontal and

\textsuperscript{64} Id.

\textsuperscript{65} Id.

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vertical agreements the legal certainty under the antitrust law. There are various forms of such agreements that may be entered into by different segments of the health care delivery industry which can be anti-competitive. The previous chapter already lays down instances of horizontal and vertical anti-competitive agreements within the concerned industry which have been identified not only in India by in other major antitrust jurisdictions as well. The antitrust agencies in the United States (FTC and US DOJ) have taken their antitrust concern towards healthcare industry a step further by issuing sector specific Guidelines which include assessment details, factors to consider and exemptions on particular aspects of the industry. Such a stand by the antitrust authorities provides a more focused antitrust enforcement in the health care industry in general and the smaller sub-markets within it.

Coming to the EU, the European Commission has over the years done away with the tedious and time consuming process of individual notification for exemption and introduced the present method of block exemptions. This method has introduced the concept and process of ‘self evaluating’ the agreements amongst the parties to assess it from the point of antitrust violation. Such a step has bought in more clarity and stability to not only the understanding of the antitrust policy and law in the EU but also better functioning and confidence in the various markets. Though there exists no specific guidelines on health care in EU, to foster competition within the healthcare sector, TFEU and various Guidelines have helped integrate EU’s antitrust activities regarding healthcare sector in a new unit called ‘Antitrust: Pharma and Health services’. This unit is responsible for ‘competition law enforcement and advocacy for all health products and services.’

3.3.4 EXEMPTIONS UNDER THE INDIAN COMPETITION LAW

The Competition Act, 2002 under Sec 3 makes certain vertical as well as horizontal agreements void due to their ‘appreciable adverse effect on competition’. The provisions under this sec have been discussed in the previous chapter at length. However, the Act provides exemptions to some of the anti-competitive agreements if the said agreements qualify them. There are exemptions mentioned specifically for horizontal agreements under

\[66\] Statements of Antitrust Enforcement Policy in Health Care, supra note 13 on 113
Sec 3(3) relating to joint ventures and generally for both vertical and horizontal agreements under Sec 3(5).

i. Joint venture defence

Under Sec 3(3) of the Competition Act joint ventures (JV) agreements which ‘increases efficiency in production, supply, distribution, storage acquisition on control of goods or provision of services’ are excluded from anti-competitive scrutiny. This exclusion is not exhaustive and explanatory. It does not give the details regarding types of JVs, the circumstances in which JVs may be notified. The Act does not define ‘joint venture’; it has to be interpreted from various case laws. In Faqir Chand Gulati case, ‘joint ventures’ connotes as association of persons or companies jointly undertaking some commercial enterprise wherein all contribute to assets and share risks.

The Indian competition law along with it Regulation is silent on the question of whether any notification or approval is required for creation of a new joint venture or for change in control of an existing JV. Even in CCI orders pertaining to combinations involving JVs, this question remains unanswered. In a recently published Frequently Asked Questions (FAQ) relating to Combinations, CCI has clarified some aspects on filing requirements under the Combination Regulations for JVs.

FAQ mentions that if transfer of assets from one company to a joint venture company is to take place then such a transaction is a ‘notifiable combination’ if the thresholds are met. Therefore, prior approval of CCI will be sought by filing forms under the Combination

70 Id.
However, the FAQs do not elaborate on whether the ‘transfer of assets’ include both ‘revenue’ and ‘non-revenue’ generating assets, thereby removing the distinction between Brownfield and Greenfield joint ventures when it comes to notification under the CCI Regulations. Under EU law, there is a sense of clarity regarding the application of law on JVs. This depends upon the inception of a JV i.e the parent companies must determine whether the newly created structure presents a full- function JVs (covered under EU Merger Regulations if the required thresholds are met) and not full- function JVs. These take the forms of a partnership formalized by a legal structure to a partnership largely dependent on its parent companies. Such JV s are not required to be notified.

The joint venture defence in India may be difficult to avail as it requires a very high burden of proof. It was considered in Jet Airways’ case by CCI. Under it the onus is on the party claiming this defence to prove that such agreement:

a. is in the form of joint venture;

b. it would result in increasing efficiency in the manufacture or provision of goods or services which;

c. outweigh the anti-competitive effects of such agreement.

Hence, though over the years, some more clarity has been bought out over this exemption, the ‘precise scope of that defence will need to be worked out in practice.’ EU competition law which has influenced Indian competition law has already placed guidelines regarding assessment of horizontal cooperation agreements. In US there are no specific guideline created by the competition agencies laying down JVs as an exemption. Most of the JVs are assessed on the basis or rule of reason in America.

JVs in the field of health care have been given sufficient explanation under the various industry based Statements issued by FTC and DOJ which have been discussed in earlier part

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75 M.P.Malhotra v Jet Airways (India) Limited, Case no 4 of 2009.

of this chapter. There have been several cases in the US which relate to JVs in the health care industry indulging in anti-competitive agreements. For example in the *Urological Stone Surgeons, Inc case*\(^{77}\), the complaint charged that three companies (Urological Stone Surgeons, Inc., Stone Centres of America, L.L.C., and Urological Services, Ltd.) and two doctors providing lithotripsy\(^{78}\) services at Parkside Kidney Stone Centres illegally fixed prices for professional urologist services for lithotripsy procedures in the Chicago metropolitan area. Urologists using the Parkside facility account for approximately 65% of urologists in the area. In it the complaint alleged that the respondents agreed to use a common billing agent (Urological Services, Ltd.), established a uniform fee for lithotripsy professional services, prepared and distributed fee schedules for lithotripsy professional services at Parkside, and billed a uniform amount either from the fee schedule or an amount negotiated on behalf of all urologists at Parkside.\(^{79}\)

The complaint also alleged that the billing agent contracted with third-party payers based on a uniform percentage discount off the urologist’s charge for professional services, or a uniform global fee that included professional services, charges for the lithotripsy machine, and anaesthesiology services. According to the complaint, the collective setting of fees for lithotripsy services was not reasonably necessary to achieve efficiencies from the legitimate joint ownership and operation of the lithotripsy machines, nor were the urologists sufficiently integrated so as to justify the agreement to fix prices for lithotripsy professional services.\(^{80}\)

A consent order was agreed upon which prohibited the respondents from fixing prices, discounts, or other terms of sale or contract for lithotripsy professional services, required the respondents to terminate third-party_payer contracts that included the challenged fees at contract-renewal time or upon written request of the payer, and required the respondents to notify the FTC at least 45 days before forming or participating in an integrated joint venture


\(^{78}\) Procedure that uses shock waves to treat certain types of stones in kidney, bladder or ureter.

\(^{79}\) Id.

\(^{80}\) Id.
to provide lithotripsy professional services. Anti-competitive practices through JVs are hence not uncommon and having a detailed guideline in assessing them is useful for curbing such practices.

In India there exists uncertainty regarding treatment meted out by CCI regarding anti-competitive practices of JVs. Further, since the joint venture defence is available only for the horizontal agreements in India, it is assumed that the prohibition of vertical agreements will be tested based on ‘rule of reason’. There is urgent need for elaboration on this aspect by CCI. A joint venture agreement which is among enterprises at different levels of productions or trade would also be tested keeping the efficiency it will create in mind even though the provisions do not state it specifically within the Indian law.

The present position has left a major gap in the enforcement of anti-competitive law in regards to joint ventures. Adding to this is the uncertainty that exists regarding treatment of research and development joint ventures, production joint ventures, commercialisations joint ventures and purchasing joint ventures under the competition law. Needless to state, the agreements entered between competitors within the health care delivery services e.g., amongst doctors, hospitals, medical device manufacturers, drug manufacturers or health insurance companies relating to research, innovation, purchase, production or ownership can perpetuate anti-competitive practices since there is no clarity regarding their assessment under the antitrust law of India.

ii. The IPR exception

Under the Indian competition law there is no ‘safe harbour’ or ‘block exemptions’ as present under the United States or EU competition laws. There are two clear exceptions to the rule of anti-competitive agreements whether horizontal or vertical in India which are mentioned under Sec 3(5) of the Act. These are relating to intellectual property rights (IPRs) and export cartels. According to it, the rule contained in Sec 3, which renders an anti-competitive agreement void, has limited application to any person who has been conferred the various intellectual property rights (IPRs) such as copyrights, trademarks, patents etc.

81 Id.
Reasonable conditions

Sec 3(5) of the Competition Act while creating exceptions to the rule of anti-competitive agreements in relation to IPR puts ‘reasonable conditions’ for protecting any IPR which may be imposed and they will not attract the scrutiny under Sec 3. Though the term ‘reasonable conditions’ has been placed within the section, there is no mention of its meaning and ambit anywhere within the Act. It implies that ‘unreasonable conditions’ imposed by the IPR holder attract Sec 3.\(^2\) The advocacy booklet on intellectual property rights issued by CCI\(^3\) further explains that ‘licensing arrangements likely to affect adversely the prices, quantities, qualities or varieties of goods and services will fall within the contours of competition law as long as they are not reasonable with reference to the bundle of rights that go with IPRs.’\(^4\)

The booklet explains this with an illustration:

A licensing arrangement may include restraints that adversely affect competition in markets by dividing the markets among firms that would have competed using different technologies. Similarly, an arrangement that effectively merges the Research and Development activities of two or only a few entities that could plausibly engage in R&D in the relevant field might harm competition for development of new goods and services. Exclusive licensing is another category of possible unreasonable condition. Examples of arrangements involving exclusive licensing that may give rise to competition concerns include cross licensing by parties collectively possessing market power and grant backs.\(^5\)

Considering the above, there may be number of practices in this realm of anti-competitive agreements relating to IPRs which may hamper competition. An illustrative list of few types of such practices has been mentioned in the aforesaid advocacy booklet, they are as following:

1. Patent pooling- These practices are termed restrictive when the firms which are in the manufacturing industry decide to pool their patents and agree not to grant licenses to

\(^2\) Versha Vahini, Indian Competition Law , LexisNexis, 1st Ed, (2016)
\(^4\) Id.
\(^5\) Id.
the third parties along with fixing quotas and prices. This may lead to supra normal profit earned by them along with keeping the new entrants to the market out.

2. **Tie-in arrangements**- In case of an IPR, when a licensee may be required to acquire particular goods such as unpatented raw materials solely from the patentee leading to a foreclosure of such opportunities for other producers.

3. **Continued royalty**- where an agreement which provides that the royalty must continue to be paid even after the patent has expired or that the royalties shall be payable in respect of unpatented know-hw as well as to subject matter of the patent.

4. Agreements which restrict research and development or prohibit a licensee to use rival technology.

5. A licensee may require to grant back to the licensor any knowhow or IPR acquired and not to grant licenses to anyone else. This is likely to augment the market power of the licensor in an unjustified and anti-competitive manner.

6. A licensor may fix the prices at which the licensee should sell.

7. The licensee may be restricted territorially or according to categories of customers.

8. A licensee may be coerced by the licensor to take several licenses in intellectual property even though the former may not need all of them. This is known as package licensing which may be regarded as anti-competitive.

9. A condition imposing quality control on the licensed patented product beyond those necessary for guaranteeing the effectiveness of the licensed patent may be an anticompetitive practice.

10. Restricting the right of the licensee to sell the product of the licensed know-how to persons other than those designated by the licensor may be violative of competition.

11. Imposing a trade mark use requirement on the licensee may be prejudicial to competition, as it could restrict a licensee's freedom to select a trade mark.

12. Indemnification of the licensor to meet expenses and action in infringement proceedings is likely to be regarded as anticompetitive.

13. Undue restriction on licensee's business could be anticompetitive. For instance, the field of use of a drug could be a restriction on the licensee, if it is stipulated that it

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86 Id.
87 Id.
88 Id.
89 Id.
90 Id.
should be used as medicine only for humans and not animals, even though it could be used for both.\textsuperscript{91}

14. Limiting the maximum amount of use the licensee may make of the patented invention may affect competition.

15. A condition imposed on the licensee to employ or use staff designated by the licensor is likely to be regarded as anticompetitive.\textsuperscript{92}

The above list of practices does give some direction to the IPR exception under Sec 3, however it remains largely insufficient in providing a comprehensive guideline in assessing whether an agreement falls within the realm of this exception.

\textbf{iii Export cartel}

Another exemption under Sec 3 is that given to an export cartel. A cartel generally operates when companies collude amongst themselves to fix prices of goods within the domestic market. Such cartels attract national antitrust law. A number of countries which have competition law in place including India exempts under Sec 3(5) what are known as ‘export cartel’ agreements from the competition law violation so long as such cartels ‘do not lead to injurious effects on the competition within the domestic market.’ \textbf{OECD} describes an export cartel to be ‘an agreement or arrangement between firms to change a specified export price and/or to divide export market.’\textsuperscript{93}

There are various rationales for allowing such cartels as they are said to facilitate cooperative penetration into the foreign markets, transfer income from foreign consumers to domestic producers and result in a favourable balance of trade.\textsuperscript{94} As stated by World Trade Organization background Note of 2002 on hard core cartels,\textsuperscript{95} Export cartels fix prices or outputs in the participating firms' export markets but not in their home markets. Import cartels aim to regulate the price or other terms of goods or services that are imported into the participating firms' home markets. In contrast,

\begin{itemize}
  \item \textsuperscript{91} Id.
  \item \textsuperscript{92} Id.
  \item \textsuperscript{93} Glossary of statistical terms, (Nov 9, 2017), available at https://stats.oecd.org/glossary/detail.asp?ID=3213
\end{itemize}
international cartels generally fix prices, outputs or other dimensions of competition across a number of national markets, often including but not limited to the home countries of the participating firms. Another distinguishing feature is that export cartels are exempted from the national competition laws of many countries, in some cases on a condition of public registration, whereas international cartels often are illegal and typically are carried on in secret unless and until they are investigated and disclosed."

Types of export exemption

In their paper titled ‘the changing international status of export cartel exemptions’\(^96\), the authors have classified exemptions available to export cartels in two categories:

a. Explicit exemption- These exemptions are those that are granted by the statue itself. These are further divided into exemptions which require notifications or authorisations and those which do not require notifications. Countries such as the United States and Australia have export exemption but require prior notification. Whereas Canadian competition law provides a good example of an explicit exemption without a notification requirement.

b. Implicit exemption- These exemptions exists when a national antitrust statue applies only to anti-competitive conduct affecting the domestic market. Most of EU members have implicit exemptions. Such an exemption in granted by negative implication, since the scope of the antitrust law is limited, and does not explicitly mention behaviour affecting foreign markets.\(^97\)

Other than the above there are also several nations which do not have a statutory exemption to export cartels. This occurs when price fixing is illegal, and there is not an implicit exemption, because the antitrust statue simply does not define the geographic scope of the market, nor is there an explicit exemption allowing price fixing for export-oriented activity.\(^98\)

Indian export exemption can be classified within an explicit exemption, though there are no


\(^{97}\) Id.

\(^{98}\) Id.
further regulations laid down or any form of notification requirement. However, the Act does distinguish between and exempts export cartels, as opposed to import cartel between enterprises located outside India with the aim of cartelizing in a relevant market within India.  

The most common reason for allowing such agreements is that the effects of such collusive activities are not felt within the country. However, from the antitrust perspective, the effects of export cartels can be in both domestic and foreign market

While empirical research on the effects of export cartels remains inconclusive no country has a strong incentive to ban export cartels unilaterally provided they do not adversely affect competition in domestic economies, either explicitly or implicitly. Implicit exclusions are as good as an explicit one as far as action by the home authorities is concerned. Studies have shown that fifteen countries maintain these exemptions. It may well be inferred from this treatment of export cartels under a competition regime that the same activity would be illegal if it were pursued domestically but since the exported quantities affect foreign markets and generate revenue in the process, they are exempt from the competition regime of the country. Or in other words, while monopoly rents accrue to the home country, the consumer loss due to high prices is mostly felt in the foreign (importing) countries leaving little incentive for exporting countries to regulate such activity.  

Export cartels can have indirect spill over effect of tacit collusion leading to encouragement of hard-core cartels within the exporting countries. According to David Larson’s analysis of American antitrust exemptions for export cartels, it would be ‘naïve to expect association members to ignore the domestic market while they freely discuss prices and quotas for exports…We are left with the conclusion that the creation of an export association provides an excellent chance for large oligopolists to peacefully coexist both at home and abroad.’

Further, the indirect spill over effect can also occur if an export cartel which has a strong market presence within the international market creates a worldwide shortage or artificially raise the prices worldwide way above the competitive level thereby increase indirectly the domestic prices of the products as well. Canada’s potash export cartel which has been existing for several years has been criticised for cartelization which lead to very high prices (more than 400 percent) of fertilizers and had a sever effect on countries like India and China who rely on exports ‘in order to sustain their demands and are one of the largest consumers of potash in the world.’

It is debated that overall, the effects of export cartels is mutually welfare reducing. Such export exemptions also prevent those who have the information on such cartels to assist those in other nations who have been harmed by them to further an investigation and punishment. Since they undermine international trade law as well, the issue relating to these cartels should be tackled by not only competition law but also by international trade law. From the Indian perspective specially, since no clarity or study is there upon the existence, practices, effects or treatment of export cartels, it is imperative for CCI to bridge the gaps and take urgent actions.

3.4 CONCLUSION

The Indian competition law has set in place few exemptions relating to horizontal and vertical agreements which have been kept away from antitrust scrutiny with the purpose of assisting the growth of the particular sector. However, the biggest drawbacks of these exemptions are that they remain largely unaccompanied by any guidelines or regulations which would make their exemption more effective and practical.

In EU where the relevant conditions of an EU block exemption are if satisfied (including the market threshold as well as excluded restrictions), such agreements automatically fall outside the prohibition under Art 101 of TFEU with no further assessment being required from the competition authorities, Over the years such exemptions have proved to be useful within EU especially to parties for ‘self-assessing’ their agreements and whether they comply with the EU law. Such innovative methods bring in not only better conformity of the law within the
competition law regime but also a sense of clarity and certainty in understanding and application of the particular law. Rightly stated by author Suzanne Rab in her book:

As a general proposition, it makes sense to limit exceptions and exemptions with specific conditions. Furthermore, they should be provided for only after robust analysis of the market sector and the specific circumstances of the case. That said, when applied pragmatically and carefully, the use of exemptions can contribute to the specific needs of the economy and the efficient application of competition law in particular cases.102

Health care delivery service which offer services to millions in India has been growing at an exponential rates especially through the large private sector. The Indian pharmaceutical sector has made its niche within the world economy by providing low cost generic medicines. The chances of export cartels existing within this industry fixing prices and supply of medicines outside India cannot be ignored. Leaving no authorization or notification method to trace such export cartels, they might in the long run have a deterrent effect to the domestic pharmaceutical market itself. Medical industry is largely innovation driven and various forms of JVs, R&D, specialisation agreements etc exists amongst various actors of this industry. To have lack of regulation may lead to various types of anti-competitive practices permeating within the industry making the products and services costly and less accessible. Hence, there is a need for CCI to make further rules regarding the functioning of these exemptions for better control and monitoring of the anti-competitive agreements by India.

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