

Study on Testdata Protection in India

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Preface

Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement has been a watershed in the history of intellectual property regime as it was the first attempt to set minimum standards at the global level. India being a member of World Trade Organisation, has amended, made new laws for the protection of Intellectual Property in tune with the standards set by the Agreement. Article 39 (3) of the Agreement mandates protection for the testdata submitted by the pharmaceutical and agrochemical industries for market approval. There was no consensus as to the mode of protection, due to the flexibility available within the provision and different approaches followed by member countries. While U.S and E.U gave exclusive right to use the data for a limited period of time, countries like Argentina gave only trade secret form of protection. This study is undertaken to identify the suitable mode of protection of testdata in India considering the interest of the Indian industry, while complying with the TRIPS obligations.

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We owe a great deal to the executives of different companies in the pharmaceutical and agrochemical industries for clearly expressing their opinion as to the mode of protection required for testdata. We are also thankful to the Pharmaceutical Industry Associations, particularly IDMA, IPA, and OPPI for giving their collective views on this issue. We remember with gratitude particularly Mr. Sumesh Reddy, Vice President, Dr.Reddy's Laboratories and Dr.G.G.Nair, Director, BDH Industries

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Summary

Legal protection for testdata submitted to the Government authorities for approval of drugs and chemicals for marketing originated from the Common Law principles of trade secret protection. This is based on the principles of equity and good faith. Many Common Law countries followed these principles for protection of testdata. In some countries today we see express statutory provisions for the protection of testdata.

Article 10bis of the Paris Convention was the first attempt to protect trade secret at the international level. Based on the Common Law principles, the Treaty obligates Member Countries to protect trade secrets from unfair commercial exploitation. Though there was no express provision to protect testdata submitted to regulatory authorities under this it was interpreted by many countries that the Common Law principles of trade secret protection will extend even to testdata as well. Some countries did protect testdata based on this obligation following the common law principles.

It was in Article 39(3) of the TRIPS Agreement an express obligation to protect testdata was introduced. It is evident from this provision that the obligation is based on the principles of Common Law to protect trade secrets. The fact that the provision forms part of protection of undisclosed information is a clear indication to this effect. The provision gives the Member Countries the freedom to adopt appropriate means to protect the information submitted to the Government agencies for approval of pharmaceuticals and agrochemical products. The wording of Article 39(3) gives much flexibility for Member Countries in determining the nature and extent of the obligation. The drafting history of this provision and the interpretation given to the wording make it abundantly clear that the obligation is based on Common Law principles of trade secret and it is limited in nature. The obligation arises only if the authorities require submission of confidential data. Thus if a Country decides to give approval of drugs based on the availability of the drugs in the market or published

literature on safety and efficiency and not insists on any confidential information there is no obligation under TRIPS to protect testdata. **So one of the best and easiest methods to comply with TRIPS is not to insist testdata in cases where the drug is available in the market in any part of the world or there is published literature regarding its safety and efficiency.**

The obligation to protect testdata is further limited to data generated for the approval of “new chemical entities” that require considerable effort. The obligation is to keep the information undisclosed to prevent unfair commercial utilization. The Article permit the authorities to disclose it or use it on grounds of public interest. The obligation to compensate the producer of data arises only when the information is used for commercial purposes.

WTO Members attempting to implement this obligation followed different approaches. Some developed countries like US, EU etc., provided data exclusivity for a limited period of time. The argument of the developed countries is that in case of drugs without patent protection there is considerable effort in developing the drugs and conducting trials to put it into the market and therefore they are to be protected. If there is no protection for the investment for a definite period of time there would be no incentive for developing new and useful drugs. Developing countries like Brazil, Mexico etc., followed the principles of trade secret protection. Testdata submitted to the authorities were given trade secret protection to prevent unauthorized use. This approach is based on the argument that providing data exclusivity for a limited period of time will create extended monopoly for the producer of drugs with new chemical entity and is disadvantages to the generic drug industry. This will also affect the public health requirement. There is also no obligation under TRIPS to provide data exclusivity.

As far as India is concerned we do not have a separate legislation to protect undisclosed information. Even though some courts used the Common Law principles to protect trade secrets there is no express case law creating obligation on the part of the Government agencies to maintain the confidentiality based on Common Law. The

practice followed in India is to create express obligation in the respective statutes on the part of the Government agencies to keep the information secret whenever it is needed.

As per the Drugs and Cosmetics Act, 1940 concerning the market approval of drugs and Insecticides Act, 1968 dealing with chemicals, regulatory authorities have the obligation to insist for the submission of valuable data signifying the safety and efficacy for granting market approval for new drugs and chemicals. The basis for this provision is to ensure safety and quality of the product. There is no express provision in these laws to keep the information secret if the parties so desire.

As per the existing law regulating approval of drugs we have used a broad definition for new drugs. This includes new chemical entities, new combinations, dosages and indications. Testdata of different types are insisted for providing approval of all these forms. But the Rules provide discretion to the authority to waive the data requirements in cases where the drug is already marketed in other parts of the world or there are sufficient published materials to show the safety of the drug. As per the Rule if the drug is already in the market in any other part of the world, only data of confirmatory clinical trials need be given for granting the approval to market it in India for the first time. The subsequent manufacturer of the same product in India need to give only bio-equivalence and bio-availability studies to get the approval. The full set of clinical trials as per the Rules is mandated only in case where the drug substance is marketed in India for the first time in the world. Such cases as of now are limited but may increase in the context of the introduction of product patent protection for new drugs. Conducting of confirmatory clinical trials and bio-equivalence/ bio-availability studies do not involve much effort. Based on these rules the Authorities now do not insist for clinical trial data for drugs already in the market in some part of the world. In such cases only data of confirmatory trials alone is insisted. In case of subsequent applicant seeking market approval for an approved new drug the data on bio-equivalence and bio-availability studies alone are insisted. Continuing this

approach seems good for the Indian drug manufacturers particularly the generic industry.

There is no express provision in the Act creating obligation on the part of the Drug Controller to keep the confidential testdata submitted to them for approval of new drugs to keep it in confidence. There is also no provision to prevent third parties from using such information without permission. In the above context to satisfy the minimum TRIPS obligation under Article 39(3) express provisions are necessary to protect the valuable undisclosed information provided to the authorities. Protecting it based on the principles of trade secret law seems the most viable and beneficial to the Indian Industry given their stage of growth and the challenges they face in the context of globalization and TRIPS.

It is evident that India has built a sound pharmaceutical industry to produce safe generic drugs at affordable cost to market not only in India but also for foreign markets including in the developed countries. Our field study indicates the slow transition that is taking place in the industry in the context of TRIPS Agreement and the consequent amendments introduced in the Patent Act. Though some big industries started investing money on new drug development majority survive through the manufacture of generic drugs. On the issue of testdata protection the majority expressed the view to have specific provisions in the Act based on the principles of trade secret law. Considering the present status of our industry and utilizing the flexibility available under the TRIPS Agreement we are suggesting trade secret form of protection. This is limited to cases where the Controller insists for full clinical trial data for drugs that are first introduced in the market. In other words, authority is under an obligation to insist for data only in case of new drugs that are not introduced in the market anywhere in the world. They are bound to maintain secrecy of those confidential data supplied for the market approval of new drugs. If the drug is already in the market or has enough published materials showing the safety and quality of the drug, the authority should not insist for full clinical trial data and grant the approval based on local conformatory data and bio-availability and bio-equivalent studies. This

will avoid duplication of testing, which is opposed on moral and economic grounds. This approach will make our law within TRIPS requirements with minimum obligations and maximum flexibility to enable the continued growth of our generic industry. For achieving this the following provisions may be included in the Drugs and Cosmetics Act, 1940 and Rules. They are:

1. Mandatory provision for ensuring the safety and quality of drugs.
2. Power of the DCGI to demand undisclosed information for drug approval for manufacture or import
3. Limit the data requirement to new drugs that are introduced first in India and not available in the market anywhere in the world
4. Provision creating obligation on the part of the officials in the office of Drug Controller General of India (DCGI) to keep the undisclosed information submitted to the DCGI for approval of a new drug in secret.
5. Obligation of the person submitting data to declare the status and nature of the information that require protection.
6. Power of the Central Government to disclose this information on public interest.
7. Liability of persons in the office of DCGI under the Official Secret Act, 1923 in case of unauthorized disclosure of the secret information.
8. Liability of the third parties in case of use of this information without the consent of the parties.

With reference to agricultural chemical products also the Registration Committee demand substantial data for market approval. There is no provision in the Insecticides Act providing protection for the data submitted for approval. So amendments in the similar lines need to be introduced in the Insecticides Act, 1963 and Rule to satisfy the TRIPS obligation.

Proposed Amendments to the Drugs and Cosmetic Act

(Note: We are introducing this new section to make express provision in the Act for drug approval which as of now is only in the Rules. This is needed since we are

suggesting undisclosed information form of protection for testdata submitted for approval of new drugs with liability on the officials disclosing it and third parties using the same.)

Add new Section 18A

Section 18A Prohibition and liability for disclosure of information

(1) No person shall be entitled to the licence under sub section (c) of section 10 or under sub section (c) of section 18 for a drug unless approved by the licensing authorities in accordance with the Rules prescribed under this Act.

(2) For the purpose of approval under subsection (1) the licensing authorities may insist on the submission of any information to be considered as undisclosed by the applicant.

(3) The licencing authority insisting on submission of information under sub-clause (2) for new drugs shall keep such information as undisclosed:

Provided that the government may by notification direct the authority to disclose such information in public interest based on such terms and conditions as it may deem fit.

(4) Any person violating the breach of confidence under subsection (3) may be liable to be prosecuted under the Official Secret Act, 1923.

(5) The applicant under subsection (1) shall be entitled to injunction, compensation or account of profit from any person using the information submitted under subsection (3) in violation of breach of confidence.

Proposed Amendments to the Drugs and Cosmetics Rules, 1945

Amendments to Rule 122-A (Amendments in bold letter)

(1)

(2) The importer of a new drug **that is not approved or marketed in other countries** when applying for permission under sub-rule (1) shall submit data as given in Appendix I to Schedule Y including the results of local clinical trial carried out in accordance with the guidelines specified in that Schedule and submit the report of such clinical trials in the format given in Appendix II to the said Schedule.

Provided that in case of new drugs already approved or marketed in other countries or there is adequate published evidence regarding the safety of the drug, the importer shall submit only data of local clinical trial as given in Appendix I to Schedule Y carried out in accordance with the guidelines specified in that Schedule.

Provided **further** that the requirement of submitting the results of local trials may not be necessary if the drug is of such a nature that the licensing authority may in public interest decide to grant such permission on the basis of data available from other countries

Delete last proviso

Amendments to Rule 122-B (Amendments in bold letters)

(1)

(2) The manufacturer of a new drug **that is not approved or marketed in other countries** under sub-rule (1) when applying for approval to the licensing authority mentioned in the said sub-rule, shall submit data as given in Appendix I to Schedule Y including the results of clinical trials carried out in the country in accordance with the guidelines specified in Schedule Y and submit the report of such clinical trials in the format given in Appendix II of the said Schedule.

Provided that in case of new drugs already approved or marketed in other countries or there is adequate published evidence regarding the safety of the drug, the manufacturer shall submit only data of local clinical trial as given in Appendix I to Schedule Y carried out in accordance with the guidelines specified in that Schedule.

Provided further that in case of subsequent approval for already approved new drugs as per sub-rule(1) the manufacturer shall submit only data as provided in Appendix I-A of Schedule Y.

(3)

Delete second proviso in 122-B(3)

Amendments to Form 44

Add the following after (2) D (3)

3. Specify the data that require protection as per section 18A(3) of the Act

.....

.....

4. Certified that the data specified in column 3 is data generated by us and is not disclosed to any one. This data is also not publicly available from any other source.

Introduction

Protection of testdata permitted under Article 39(3) of the TRIPS Agreement has assumed importance for each country inasmuch as it may help them to protect the interest of their industries. Testdata, broadly speaking, is data relating to quality, safety and efficacy as well as information on the composition and physical and chemical characteristics of the products, required by the national authorities as a condition for granting permission to market pharmaceutical and agricultural chemical products. Many of this information could be confidential in nature requiring protection. The justification for the protection of testdata is the considerable time and energy in terms of intellectual input needed to generate this information. It was also argued that this data might include in some case information relating to new products that may not attract patent protection. Testdata protection is the minimum incentive that is needed to encourage research to bring out such innovative products. It is the competitive advantage that is enjoyed by the first producer of data against subsequent entrant of similar product (generic) in the market that make testdata protection sensitive and controversial.

Historically testdata submitted to governmental agencies were protected in developed countries by way of Common Law principles of trade secret. There were many exceptions to this based on public interest. Unsatisfied by this practice, the companies interested in research successfully lobbied the governments in certain countries like US and EU, to grant exclusive right over this data on the ground of incurring huge expenditure. But many developing countries do not have any law to protect testdata irrespective of the fact that their government agencies demand confidential data for the purpose of market approval of the products.

Article 39(3) of the TRIPS Agreement is the first attempt to create an international obligation to protect testdata. This provision mandate protection against unfair commercial use of testdata demanded by the government agencies under the title confidential information. Different modes of protection followed in different

countries along with the flexibility of the wordings in Article 39(3) gave rise to conflicting interpretation. It is argued by the developed countries particularly EU and US that this provision mandates providing exclusive private property protection in the form of data exclusivity for a specific period of time. On the other hand, the developing countries argue that the obligation is limited to the one similar to that of protecting trade secret.

As far as India is concerned under the Drugs and Cosmetic Act, 1940 and The Insecticides Act, 1968 the government agencies have the power to demand data for the purpose of granting approval of the marketing of drugs and insecticides. They do in fact demand data for this purpose. There is no express provision in these laws providing protection for the data submitted to the authorities. It is evident that as per Article 39(3) India has an obligation to provide some form of protection to the confidential testdata submitted to the authorities. In the context of conflicting interpretation given to this provision this study aims at finding out the nature of obligation mandated by this provision and suggest appropriate amendments to the Indian laws to satisfy the minimum TRIPS obligation.

First chapter of the study traces the history of protection of undisclosed information under common law and the protection given to testdata under it. Based on the case law from England, US, Australia etc., it is clear that the common law approach is a balanced one keeping in mind the private and public interest involved in protecting testdata. Second chapter makes a detailed analysis of TRIPS provisions to identify the exact obligation emanating from it. The obligation under Paris Convention regarding testdata protection and the practice followed by different countries in protecting testdata also form part of this chapter. Based on the analysis it is concluded that the minimum obligation under TRIPS is to provide effective trade secret form of protection to testdata. Third chapter deals with Indian legal position of trade secret and legal provisions under drug laws demanding the submission of testdata. Various provisions of the Drugs and Cosmetic Act and the Insecticides Act are examined in detail to find out the nature of data demanded by the authorities and their legal

obligation to protect the same. A limited but representative field study of the perspective of the Indian Pharmaceutical Industry on testdata protection is reflected in the fourth chapter. Based on this the study concludes that the Indian laws require amendments to discharge the TRIPS obligation. Suggestions are given to amend the laws following the principles of trade secret protection.

Chapter I

Protection of Undisclosed Information – A Common Law Perspective

Undisclosed information, commonly known as trade secrets, are identifiable items or compilations of information relating to a business, which rely for their value on being not generally known and which give that business a competitive edge over its rivals.¹ It plays a significant economic role.² It provide the lead time advantage to the owner over his rivals as well as an incentive to develop incremental innovation of technology not meeting the non obviousness standard of patent law, or where patents and copyrights are unavailable, ineffectual or unattractive.³ Legal protection of trade secret also reduces the wasteful expenditure to be spent by the trade secret owner to protect its secrecy.⁴ In certain circumstances, these secrets are bound to be communicated to the state agency in the larger interest of public. In order to understand the status of such information, a brief analysis of development of concept of trade secret is necessary.

Development of the Concept of Trade Secret under Common Law

The concept of trade secret appears to be easy for description. The legal means through which its protection is sought is amorphous. Essentially devices for protection have been developed by courts in course of time to suit the needs of the time and therefore it is hardly possible to identify any particular principle. The courts employed the principles of contract, trust, property and equitable concepts of good faith and

¹ Trade secrets are a species of confidential information, which includes extremely personal and intimate information to the highly commercial and technical data. See John Hull, *Commercial Secrecy Law and Practice*, Sweet & Maxwell, London, (1998) at p.1.

² Friedman, Landes and Prosser, "Some Economics of Trade Secret Law", in Towse and Holzhauser, *The Economics of Intellectual Property*, Vol.III, EE Publishing Ltd., UK, (2002) at pp.230-241.

³ See Edmund W. Kitch, "The Law and Economics of Rights in valuable Information", in Towse and Holzhauser, *The Economics of Intellectual Property*, Vol. III, EE Publishing Ltd., UK, (2002) at pp. 175-215.

⁴ David Friedman, "Trade Secret", in Towse and Holzhauser, *The Economics of Intellectual Property*, Vol. III, EE Publishing Ltd., UK, (2002) at pp.171-173.

fiduciary duty depending upon the circumstances presented in the case to afford protection. Thus there is no legal pigeon hole into which the law of commercial secret fits. Now, the principles of equity and law are interwoven to grant protection to trade secrets.

Justification for Trade Secret Protection

Different arguments based on property right⁵ or the economic incentive⁶ or commercial ethics have been raised in support of the protection of undisclosed information. But the strong argument appears to be the one based on commercial ethics, because trade secrets are protected to create an atmosphere conducive to the development of commercial transactions. In other words, businessman disclosing secret to one another are entitled to believe that their secrets will be respected and kept and the existence of a law of commercial secrets helps to sustain that expectation.

The development of trade secret law can be traced to the traditional English concept of sanctity of contract.⁷ However the equitable jurisdiction in cases of breach of confidence was used earlier also. In the first reported cases on trade secrets, courts accepted breach of trust, as the principal basis of court's jurisdiction though breach of confidence had also been mentioned as a separate ground for intervention.⁸

Two cases, decided in the midst of 19th century, *Prince Albert v. Strange*⁹ and *Morison v. Moot*, can be regarded as a watershed in early judicial efforts to establish a cause of action based on breach of confidence alone. But, a clear legal frame work was given to the concept of trade secret in *Saltman Engineering Co. Ltd v. Campbell*

⁵ See *Ruckel Shaus v. Monsanto Co.*, 467 US 986. The US Supreme Court held that Disclosure of Health and Safety data by the authorities will amount to taking for Fifth Amendment in the US Constitution. For a detailed discussion see Roger M. Milgrim, *Milgrim on Trade Secrets*, Lexis Nexis, 2002, Chapter 2; Steven N.S. Cheung, "Property Rights in Trade Secrets", in Towse and Holzhauser, *The Economics of Intellectual Property*, Vol. III, EE Publishing Ltd., UK, (2002) and Andrew Mitchell, "The Jurisdictional Basis of Trade Secret Actions: Economic and Doctrinal Considerations", 8 A.I.P.J.137 (1997). But it has now become an academic discussion.

⁶ See *Kewanee v. Bicron*, 416 U.S. 470 (1974).

⁷ David Vaver, "Trade Secrets – A Common Wealth Perspective", 9 E.I.P.R. 301 [1979].

⁸ *Supra* n.1 at p.24.

*Engineering Co.Ltd.*¹⁰ In this Lord Greene., M.R. negated the requirement of a contract for creating an obligation of confidence.¹¹ He said:

“If a defendant is proved to have used confidential information directly or indirectly obtained from a plaintiff, without the consent express or implied of the plaintiff, he will be guilty of an infringement of the plaintiff’s rights”¹².

Concept of breach of confidence was strengthened by Lord Denning in *Seager v. Copydex*¹³ by adding another principle thus:

“As I understand it, the essence of this branch of law, whatever the origin of it may be, is that a person who has obtained information in confidence is not allowed to use it as a springboard for activities detrimental to the person who made the confidential communication and spring board it remains even when all the features have been published or can be ascertained by actual inspection by any member of the public.

The law on this subject does not depend on any implied contract. It depends on the broad principle of equity that he who has received information in confidence shall not take unfair advantages of it. He must not make use of it to the prejudice of him who gave it without obtaining his consent.”¹⁴

The basis of the action was expanded to the broad principle of equity not to take unfair advantage of information given in confidence.

⁹ See J.Philips, “ Prince Albert and the Etchings”, [1984] 6 E.I.P.R. 344.

¹⁰ [1963] 3 All E.R. 413.

¹¹ The observation of the judge is noteworthy. “If two parties make a contract, under which one of them obtains for the purpose of the contract or in connection with it some confidential matter, then even though the contract is silent on the matter of confidence, the law will imply an obligation to treat that confidential matter in a confidential way, as one of the implied terms of the contract. but the obligation to respect confidence is not limited to cases where the parties are in contractual relationship.” *Ibid.* at p. 414.

¹² *Ibid.*

¹³ [1967] 2 All E.R.415.

¹⁴ *Ibid.* at p. 417.

The jurisdiction on equity was confirmed by Lord Denning in *Fraser v. Evans*¹⁵ by declaring that, the jurisdiction is based, not so much on property or an contract but rather on the duty to be of good faith. Thus a duty not to take unfair advantage and a duty of good faith became the guiding principles for a breach of confidence action based in equity.

In *Coco v. A.N. Clark (Engineers) Limited*,¹⁶ Megarry., J, summarized the essential elements of the action for breach of confidence by referring to the earlier decisions thus:

- i. Information must have necessary quality of confidence about it.
- ii. The information must have been imparted in circumstances importing an obligation of confidence.
- iii. There must be an unauthorised use of that information to the detriment of the party communicating it.

Thus the development of breach of confidence¹⁷ was the creation of judges in the larger public interest of creating an atmosphere conducive for conducting business. In other words, ultimate basis for the protection of confidence is not, the private interest of the party to whom the confidence is owed, but the public interest that confidence, even of a professional or commercial nature, should be respected. Thus the protection of trade secret is not absolute in its nature. In certain circumstances the public interest in maintaining confidence has to be balanced against a counter-veiling public interest that would be served by discharge of the confidential information.¹⁸

¹⁵ [1969]1 All E.R. 8.

¹⁶ [1968] F.S.R. 415.

¹⁷ For an exhaustive examination of the law relating to confidentiality see *AG v. Guardian Newspapers Ltd., and others* (No.2), [1988] 3 All E.R.545.

¹⁸ Public interest exception to the duty of confidentiality appeared almost at the nineteenth century birth of the duty of confidence in *Gartside v. Outram* was that “there is no confidence as to the disclosure of iniquity.” Later the iniquity rule was widened to include any misconduct of such a nature that it ought in the public interest to be disclosed to others. An approach of balancing the conflicting interests in maintaining the confidence and disclosure of information was also highlighted. See Finn, “Confidentiality and the Public Interest”, 58 *Australian Law Journal* 497 (1984) and Hazel Carty, “Employee Confidentiality and Disclosure in the Public Interest”, [1985] 7 E.I.P.R.195. See also *Initial Services Ltd., v. Putterill*, [1967]3 All E.R.145, *Fraser v. Evans*, [1969]1 All E.R.8 and *Lion Laboratories v. Evans*, [1984]2 All E.R. 417.

Protection of Testdata under Common Law

State regulatory agencies, in many circumstances demand lot of information from the persons, companies or organisations having operations affecting the public. For example State require reports on the safety of drugs in discharge of its duty to ensure the safety of the drugs available in the market. Before the authorisation for use or sale of a drug, the State will demand information requiring its safety, efficacy, composition, method of manufacture etc. Among these information, some of them may be of confidential in nature, retained by the companies to maintain its competitive advantages. This raises the question as to status of these information after they are released to the Government authorities. House of Lords in *Norwich Pharmacal Ltd. v. Communication of Customs and Excise*¹⁹ ruled that the State agency has an obligation to maintain confidentiality of information arising from disclosure pursuant to statutory obligation or by voluntary discharge made by any person. In other words, if the information have the necessary degree of confidentiality, it will not be discharged through disclosure made to a State body or under compulsion of State. The agency or department receiving information is under a duty not to use it except for the specific purpose for which it was disclosed or not to disclose it to those unconnected with that purpose.

Thus, the State agency is also under an obligation to maintain the confidentiality of these data as in the case of any other person. But public authorities exercising important functions in the public interest cannot be restricted to very limited uses on the ground of breach of confidence. The question that usually arises is that the extent to which the authority can use this information. The general question of the creation of an obligation by disclosure to a State agency was reviewed recently by English courts in an action brought by a pharmaceutical company claiming to protect information submitted to support a product licence application for the drug cimetidine. SmithKline & French Laboratories were the owners of two patents relating to

¹⁹ [1973]2 All E.R.943.

cimetidine, both of which were about to enter their licence of right phase. SKF had supplied the licensing authorities with considerable amount of information relating to testing and research on the drug so that product licence would be obtained. The action considered whether information supplied to the licensing authority by SKF could be used by the Authority for grant of approval to other manufacturers of generic products on the ground of essential similarity. Henry J's decision, restraining the licensing authority from using the SKF's data for granting approval to generic manufactures was reversed by Court of Appeal based on the ground of public health under the European community law.²⁰ It accepted the principle of an obligation of confidentiality attaching to the licensing authority. The authority could use the information supplied by SKF for performing its statutory functions including of granting product licences for generic drugs. But the disclosure of the SKF information would however amount to breach of duty of confidence.

The House of Lords concluded that the English domestic law of confidence does not prevent the licensing authority from making use of the information supplied by the appellants for any of the purposes for which the licensing authority was established.²¹ The observations of the court are noteworthy:

“It is for the licensing authority, comparing the information received from the first applicant and the other information received from the second applicant, and taking into account all other information available to the licensing authority, from whatever source and whether confidential or not confidential, to decide in the case of any particular application whether it shall be declined or granted. There may be, there will be, in the case of a popular medicinal product many applications by, many different applicants. It is essential for the licensing authority to compare the applications of the first and subsequent

²⁰ *R v. Licensing Authority, ex parte SmithKline & French Laboratories Ltd., (Generics (UK) Ltd., and another intervening*, [1989]1 All E.R. 175.

²¹ *SmithKline & French Laboratories Ltd., v. Licensing Authority*, [1989]1 All. E.R. 578. See also Tania Voon, “Breach of Confidence by Government, Smithkline and the TRIPs Agreement –Public Interest to the Rescue”, 9 A.I.P.J. 66 (1998).

applicants in order to satisfy themselves that both products are similar, safe, effective and reliable. The licensing authority cannot discharge its duty to safeguard the health of the nation and its duty to act fairly and equally between applicants without having recourse to all the information available to the licensing authority, confidential or otherwise. Indeed, it would not be practicable and it would be highly dangerous for the licensing authority to attempt to segregate in the case of each applicant the information which was confidential to that applicant and to forget or ignore that information when carrying out any function imposed on the licensing authority by the 1968 Act in the interests of the public.”²²

Thus the obligation of the regulatory agencies is to maintain the confidentiality of the information. It can disclose it only in cases of exceptions of public interest. But the authority is free to utilise information for the performance of its statutory functions under the relevant Act.

Thus it can be inferred that testdata supplied by the drug or agrochemical manufacturer is given an adequate protection under the common law.

²² [1989]1 All. E.R. 578 at p. 587.

Chapter II

Protection of Testdata under TRIPS Agreement

Protection of undisclosed information has never been subjected to international protection till recently. The provision in the Paris Convention relating to prevention of unfair competition has been interpreted to create obligation to protect undisclosed information¹. Article 39 of the TRIPS Agreement is the first instance where a binding obligation to protect ‘undisclosed information’ has been expressly brought under the purview of an international agreement on Intellectual Property Rights. The mandate to protect ‘undisclosed information’ and ‘data submitted to governments or governmental agencies’ was an attempt to concretise the concept of unfair competition as originated in Paris Convention.²

Paris Convention and Undisclosed Information

By the end of 19th century, English Legal System through the devices of passing off³, injurious falsehood⁴, unlawful interference with trade⁵ and breach of confidence⁶ prohibited various acts, which distorted the commercial atmosphere to ensure healthy competition.⁷ Though unfair competition was not accepted as an

¹ Paris Convention (1967) Article 10bis read: (1) “The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition. (2) Any act of competition contrary to honest practices in industrial or commercial matters constitute an act of unfair competition.....”

²Article 39(1) reads as follows: “In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with Paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.”

³ See *Reddaway v. Benham*, (1892) 2 Q.B.639 and *Cellular Clothing Ltd., v. Maxton*, (1899) A.C.326.

⁴See *Ratcliffe v. Evans*, (1892) 2 Q.B. 524.

⁵ See Rogers, *Winfield and Jolowicz on Tort*, Sweet & Maxwell, London, (13th edn. 1989) at pp.495-542.

⁶ See Chapter I.

⁷ See G.Dworkin, “Unfair Competition: Is the Common Law Developing a New Tort?”, [1979] 9 E.I.P.R. 241 and Development in the Law, “Competitive Torts”, 77 Harv.L.R.936 (1964) .

autonomous principle of tort⁸ the use of various tort principles to prohibit dishonest trade practices served the purpose of maintaining commercial ethics. In the US the concept of unfair competition found its roots in ‘passing off’⁹ and grew into a comprehensive one encompassing all unfair practices that are used in the competitive market environment.¹⁰ The Civil Law countries modified their codes and statutes incorporating these principles to ensure healthy competition in the market.¹¹ Even then the concept of unfair competition was confusing as to its nature and content. As the trade started crossing national boundaries, the need to regulate unfair competition was felt at the international level. Article 10bis of Paris Convention was the result.¹² Article 10bis assured nationals of member countries effective protection against unfair competition.¹³ It defined an act of unfair competition as “any act of competition contrary to honest practices in industrial or commercial matters”.¹⁴ It also listed three self-executing examples of unfair competition, which include confusing or misleading the customer and discrediting the competitor¹⁵. The definition appears to be so wide and flexible to include all kinds of dishonest practices accepted in different legal

⁸ Recently demand for a general action for unfair competition is gathering momentum. See H. Brett, “Unfair Competition – Not an Academic Issue?”, 11 E.I.P.R.295 [1979]; J. Lahore, “The Pub Squash Case, Legal Theft or Free Competition”, 2 E.I.P.R.54 [1981]; P. Burns, “Unfair Competition a Compelling Need Unmet”, 11 E.I.P.R. 311[1981]; J. Adams, “Is there a Tort of Unfair Competition? Legal Protection of Advertising Campaigns and Merchandising”, JBL 26 [1985] and A. Booy, “A Half way House for Unfair Competition in the United Kingdom—A Practitioners Plea”, 12 E.I.P.R. 439 [1991]. For a contrary view see M. Spence, “Passing Off and the Misappropriation of Valuable Intangibles”, 112 L.Q.R.472 (1996).

⁹ In U.S. Unfair Competition was used as synonym of Passing Off. See Chafee, “Unfair Competition”, 53 Harv.L.R. 1289 (1940) at p. 1296, Developments in the Law, “Trademarks and Unfair Competition”, 68 Harv.L.R. 814 (1955) at p. 818.

¹⁰ To know the earlier trend see O.R. Mitchell, “Unfair Competition”, 10 Harv.L.R.275 (1896-97). Unfair Competition was accepted as an autonomous doctrine in *International News Service v. Associated Press*, 248 US 215 (1918).

¹¹ Sanders, *Unfair Competition Law The Protection of Intellectual and Industrial Creativity*, Clarendon Press, Oxford, (1997) at pp. 24-49.

¹² It was adopted in Revision conference of Brussels in 1900. See Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property*, BIRPI, Geneva (Reprint, 1991) at p.142.

¹³ Article 10bis (1) read: “The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition”.

¹⁴ Article 10bis (2).

¹⁵ Article 10bis (3) read: “The following particular shall be prohibited: (1) all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor (2) false allegations in the course of trade of such a nature as to discredit the establishment, the goods or the industrial or commercial activities of a competitor (3) indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quality of the goods.

systems. The examples given in clause (3) are not exhaustive and they prescribe only the minimum type of practices of unfair competition against which protection should be secured.¹⁶

Though misappropriation of trade secrets or confidential information was not included in Article 10bis (3), protection of industrial and business secrets is implied by the general obligation of Article 10bis (1) and (2).¹⁷ The translation of this obligation found different ways in different countries, particularly between civil law and common law countries. Civil law countries protected trade secret through specific legislation against unfair competition¹⁸, whereas common law countries, used the common law of tort and breach of confidence¹⁹. This difference in the devices was well accepted by the international community.²⁰ Thus the concept of breach of confidence evolved by the common law courts was recognised as an effective legal tool to satisfy the obligation under Paris Convention.

Protection of Undisclosed Information under TRIPS Agreement

Article 39 dealing with protection of undisclosed information was formulated after compromising different conflicting approaches to the protection of trade secret followed by different countries.²¹ European Union's proposal based on principles of unfair competition provided under Paris Convention prevailed over the suggestion

¹⁶ See Bodenhausen *op.cit.* at p. 145.

¹⁷ Jayasree Watal, *Intellectual Property Rights in the WTO and Developing Countries*, Oxford (2000) at p. 186. See Article 6 of Model Provisions on Protection against Unfair Competition drafted by WIPO (WIPO document, Protection against Unfair Competition 1994, Geneva, WIPO Publication No.725(E) .

¹⁸ For example Unfair Competition Law of Germany and Japan has trade secret protection provisions.

¹⁹ See Chapter I.

²⁰ This difference was not only in the protection of trade secrets but was also in the protection against unfair competition. But it was admitted at several revision conferences that member states are not obliged to introduce special legislation to this effect if their existing general legislation. For example provisions of civil law directed against torts or principles of common law suffices to assure effective protection against unfair competition. See Bodenhausen *op.cit.* at p.143.

²¹ Apart from the difference in the form of protection to be given to the confidential information, Developing countries like India, Brazil and Peru objected to the inclusion of confidential information as an intellectual property. See F. Dessemontier, "Protection of Trade Secrets and Confidential information", in Correa & Yusuf (Eds.), *Intellectual Property and International Trade*, Kluwer Law International, London at p. 238.

proposed by the US²² to consider undisclosed information as a form of property.²³ Thus Article 39 was drafted to ensure effective protection against unfair competition under Article 10bis of Paris Convention. It was also argued that, since the trade secret protection was not included in the self executing instances of unfair competition under Article 10bis(3), TRIPS provisions amount to concretisation of the provision in the Paris Convention.²⁴ Article 39 (1) corroborates this argument. It reads as follows:

“In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with Paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3”.

The essentials of an undisclosed information are described in Paragraph 2 of Article 39. It mandates provisions in the laws of member countries empowering natural and legal persons to prevent any information lawfully within their control from disclosure, acquisition or use by others without their consent. The information must be secret, having commercial value, and the person lawfully in control of the information has taken reasonable steps to keep it secret.²⁵ Reference is also made to ‘honest commercial practices’ i.e., the general criterion for honest competition as set out in

²² UNCTAD/ITCDS, *Development Resource Book: Substantive Obligations on Undisclosed information*, 2002.

²³ U.S. accepted Trade Secret as a property. For a detailed discussion see Roger M. Milgrim, *Milgrim on Trade Secrets*, Lexis Nexis, at pp. 2.01-2.44

²⁴ R. Krasser, “The Protection of Trade Secrets in the TRIPS Agreement”, in Beir and Shriker (Eds.), *From GATT to TRIPS- The Agreement on Trade Related Aspects of Intellectual Property Rights*, Vol.18, IIC Studies, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, Munich, (1996) at p. 216.

²⁵ Article 39(2) read: “Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is secret; and (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret. For a detailed analysis of these provisions, See Daniel Gervais, *The TRIPS Agreement Drafting History and Analysis*, Sweet & Maxwell, London (1998) at pp. 181-88 and S.K. Verma, “Protection of Trade Secrets under the TRIPS Agreement and Developing Countries”, 5 J.W.I.P. 727 (1998).

Article 10^{bis} (2) of the Paris convention.²⁶ These provisions are substantially based on the Uniform Trade Secrets Act of the US and the principles enunciated in the case law in that country.²⁷ This in essence also reflects the common law principles of trade secrets as laid down by the courts.²⁸

Protection of Testdata before TRIPS Agreement

Prior to TRIPS agreement there was no law for the protection of testdata at the international level. In common law jurisdictions, undisclosed data submitted to government authorities for regulatory approval was protected under the principles of breach of confidence. Health authorities were permitted to rely on the first application data for the evaluation of second entrant application for similar products²⁹. Later as a result of industry lobbying, some developed countries such as US and EU adopted the concept of data exclusivity.³⁰ During the exclusivity period subsequent applicants cannot rely on an originator's test data to approve their application without the originators consent. Thus there is a disparity in the mode of protection given to confidential information submitted to Government Agencies in different countries.

Data Exclusivity - Conceptual Analysis

Protection of testdata by granting data exclusivity for a specific period signifies the balance between different arguments in support of disclosure and non-disclosure of health and safety information. It is argued that disclosure of health and safety data submitted to administrative agencies will enable it to improve the quality of its decisions with the assistance of comments made by independent scientific and public

²⁶ Footnote to Article 39 (3) read: "For the purpose of this provision, " a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition".

²⁷ See Jayasree Watal, *op.cit.* at p. 192.

²⁸ See Chapter 1.

²⁹ *Ibid.*

³⁰ For a detailed discussion see Trevor M. Cook, *Special report on the protection of regulatory data in the pharmaceutical and other sectors*, Sweet & Maxwell, London (2000).