



Trade Secret Protection in Ayurveda: Examining the Need for a Legislation

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India does not have a separate legislation for trade secret protection and moreover has been following the UK model for trade secret protection. Many of the Indian courts have cited English decisions in their judgements. The National Innovation Bill, 2008 was an effort initiated by the Ministry of Science and Technology to create a legislation with respect to protection of confidential information, however it was not tabled in the Parliament. A need for a separate law for trade secret protection was identified in the 161st Report on Review of the Intellectual Property Rights Regime in India of the Parliamentary Committee, where it was observed that there is lack of clarity on several aspects in the current framework of protecting trade secrets in India. One of the important inquiries to be undertaken is whether there is a dire need in the Indian industry for a legislation. Hence, an empirical study was carried out to understand the trade secret practices adopted by the Indian industry. For this purpose, a limited case study about industrial practices relating to trade secret protection in the Ayurveda industry was conducted. Empirical evidence shows that even though the industry is actively indulging in trade secrecy, the contribution of the current legal mechanism in this regard is very minimal. The industry experience strongly suggests that there is no need for a separate legislation.

Keywords: Trade Secret in Ayurveda, Proprietary Medicine, Trade Secret Legislation, Reverse Engineering, Kerala Ayurveda, Innovation, Drugs and Cosmetics Act

Protection of trade secrets in India is still afforded by the courts mostly following the English model based on the principles of equity, common law action of breach of confidence and contract law. The Parliamentary Committee on Commerce, in July 2021, recommended the enactment of a separate legislation or framework for the protection of trade secrets in India.¹ Prior to this, there have been repeated demands from the US predominantly through the Special 301 Report² to strengthen the enforcement mechanism of trade secrets in India. However, a concrete study backed by data has not been conducted to verify whether India requires a legislation for the protection of trade secrets. The general assumption is that stronger trade secret laws work against society as incomplete disclosure adversely affects further technological advancements, and undermines the objectives of different IP rights.³

Hence an empirical study was undertaken to examine whether there is any need for a separate legislation considering the ground reality of industrial practices in the Kerala Ayurveda Sector.

Research Methodology

The method used for collecting information is through semi-structured questionnaire following convenient sampling. The study was based on the Ayurveda Industry in Kerala.

The COVID 19 related restrictions and protocols issued by the Union and State governments and the subsequent travel restrictions also restricted the study to the State of Kerala. Language was another barrier to conducting sampling in other States, especially due to the nature of the study being conducted. Unlike other intellectual property, in the case of trade secrets, participants are more apprehensive about the safety of the confidential information which they hold. Hence, references from known persons had to be used for extracting information from the participants.

The Ayurveda sector was selected for study since it was observed from a pilot study that the industry had been using trade secrets to promote their trade. Moreover, the existing literature⁴ also confirmed the presence of trade secrets in the industry. Additionally, the Ayurveda industry is selected since it is an industry where India has proved its strong presence both in the national and international markets. Moreover, it is an industry where secrecy is maintained with respect to the processes and

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products of Ayurvedic formulations.⁵ The study conducted looked into the trade secret practices of the industry, mainly focussing on aspects such as:

- a) Measures taken to protect secrets
- b) Misappropriation
- c) Enforcement
- d) Reliance on other IP and
- e) Other measures adopted to overcome competition

The Kerala Ayurveda sector was selected for sampling purposes in this study also for the reason that Kerala constitutes a large portion of the Ayurveda sector and can be considered as one of the states where the roots of Ayurveda can be traced.⁶ Kerala is also one of the states where the highest number of manufacturing units for Ayurvedic medicines are situated.⁷ For the purpose of the study, 10 units were taken based on the market share of the participants.⁸

Ayurveda Industry of Kerala

Ayurveda is part of the culture and tradition of India. The word Ayurveda originated from the combination of the two Sanskrit words “Ayur” which means life and “Veda” which refers to knowledge of the ancient Indian texts, in this case referring to the ‘Atharva Veda’.⁹ Ayurveda is recognised as an indigenous system of medicine, boasting a history of 5000 years, which includes both, medicinal products and health services.¹⁰ According to statistics from MRC, the Global Ayurveda Industry is estimated at USD 3.428 billion in 2015 and is expected to reach USD 9.971 billion by 2022.¹¹ Whereas the Confederation of Indian Industry (CII) estimated the Indian Ayurveda Industry at USD 3 billion and is expected to reach USD 9 billion by 2022.¹¹ In the year 2017-2018, the Industry has a trade surplus of USD 130.48 million.¹² The survey conducted by CII shows growth projections across different sub-sectors of Ayurveda with an overall CAGR (Compound Annual Growth Rate) of 16 percent by 2022.¹¹

Before the British rule had established its strong presence throughout India, Ayurveda, was the system of medicine that had been relied upon by a substantial number of people in India.¹³ However, it was not in the form of an organized industry as we see it today. Medicines and treatments were provided by various families who passed on their traditions from generation to generation. Rituals, hymns and prayers were a part of the medicine preparations. Even for handpicking raw materials, certain rules were to be followed.¹⁴ Ayurveda as we understand it today is

largely based on recognized traditional classical texts.¹⁵ Still, keeping the information developed by the families as a secret seems part of the culture in Ayurveda. In the present times, the Ayurveda system of medicine has turned into an organized industry owing to the consumer preferences inside and outside the country. Standardization of production, the institutionalization of education and the professionalization of Ayurvedic practice has largely contributed to the growth of this industry.¹⁶ Different formulations are now available in capsule form for the convenience of consumers. While undergoing the process of adapting to the industry requirements, this system too has not been spared from the influence of the western system of propertization. Players in the industry have explored all possible ways to maintain exclusivity in the market, in order to have a competitive edge over other players. Intellectual property rights such as trademarks and patents have been used by companies manufacturing Ayurvedic medicines, in order to protect their brand names and products.¹⁷ However, in ancient times when none of the formalized intellectual property rights existed, certain practices were adopted in order to maintain the secrecy of the knowledge with respect to the formulations and knowledge of Ayurvedic medicines.¹⁸ This prevented people outside the families from appropriating the knowledge acquired and passed on from generation to generation.¹⁸ This practice is also followed by industries in cases where they developed new formulations. Hence the inquiry is to find out how far has the Ayurveda industry shifted from the informal protection of secrecy to the formal legal mechanism for trade secret protection utilizing the existing legal framework in India. This will further answer the larger question, of whether there is any demand for separate legislation from a trade secret-dependent industry like Ayurveda.

Innovations in Ayurveda

As far as Ayurvedic medicines are concerned, the two important factors are shelf life and palatability. Those products in the market which are able to deliver good results with respect to these factors are favoured by most consumers. These in one way can be termed as innovations brought about by Ayurvedic firms to their products.¹⁹ Certain firms, mostly the large ones are involved in the making of new products and processes, which can be termed as major deviations from classical text medicines.¹⁹ The industry has to

comply with certain legal requirements before introducing these new products into the market.

Legal Mechanism in India

The Drugs and Cosmetics Act, 1940 governs the regulation of the industrial production and distribution of Ayurvedic medicines. The Act lists the Ayurvedic medicines into two categories:

- i) Classical Text Medicines, and
- ii) Patent or Proprietary Medicines

As per the Act, a license is required from the Drugs Controller under the Act to manufacture and sell any Ayurvedic medicines.²⁰ Classical text medicines refer to medicines prepared according to the formulae mentioned in the authoritative books mentioned in the First schedule of the Drugs and Cosmetics Act.²¹ An industry seeking a licence to produce medicines based on classical text need not produce any additional evidence to prove the safety and efficacy of the medicine since it is produced based on the formulae and method of preparation mentioned in the text. Patent or proprietary medicines refer to the medicines prepared according to formulae which is not mentioned in the authoritative books in the First Schedule. However, the ingredients are largely based on the authoritative texts mentioned in the Act.²² Even those medicines which are a result of minor tweaking to the classical Ayurvedic medicines fall under the category of “patent or proprietary medicines”.²³ Interestingly, a major share of the Ayurveda market is dominated by proprietary medicines.²⁴

The term “patent or proprietary medicine” was made applicable to Ayurveda since 1964.²⁵ Ayurvedic medicines, which consisted of different formulae were provided a route of registration under the Drugs and Cosmetics Act to facilitate the exclusive use of the medicine. The approval of these medicines is not based on the patentability criteria mentioned under the Indian Patents Act, 1970. Such a system of exclusivity runs parallel to the exclusivity provided under the Patent Act.²⁶ A license is granted for marketing the preparation under the label “patent or proprietary medicine”.

The Patent or Proprietary Medicine Conundrum

In order to obtain a license for a proprietary medicine, the manufacturer of Ayurvedic medicine is required to submit data with respect to the safety and efficacy of the medicine.²⁷ Earlier, such a requirement was absent and hence made the approval of such

medicines easier.²⁸ Over the years, the requirements for approval of a proprietary medicines have undergone many changes which have resulted in a lesser rate of approval of proprietary medicines, especially in Kerala.²⁹ It is reported that in other States, even now the requirements are bypassed, therefore creating a trend of seeking a license from other States.³⁰

The formula of the proprietary medicine needs to be submitted before the Drug Controller and once the license is granted, the owner of the proprietary medicine has the exclusive license to market the medicine.³¹ The license is granted for a period of 5 years, following which the manufacturer has to apply for renewal of the license.³¹ Any third party using this formula for manufacturing and marketing an Ayurvedic medicine can be prevented from such use.

Even though the applicant of proprietary medicine is required under the Act to disclose the true formula of the medicine on the label,³² certain aspects of the formula, such as the method and proportion in which the ingredients are mixed remain a secret. There are certain studies that even indicate the deficiency of information with respect to the ingredients of such medicines.³³

Role of Trade Secrets in Ayurveda

As stated in the beginning, the knowledge of ingredients and way of preparation of some of the Ayurvedic medicines were confined to the members of a family.³⁴ In the olden days, some of the Ayurvedic formulations used to be engraved on palm leaves and were only accessible to a few members of the family. This knowledge would be passed on to the next generation of members by the elderly members of the family in order to keep alive their family traditions.³⁵ When we come to the industry settings today, it is observed that most of them have evolved from the pre-existing families who practiced the tradition and hence are owned by them and the ownership is being transferred to their legal heirs like in old times.³⁵ However, since the enactment of the Drugs and Cosmetics Act, and the introduction of the concept of patent or proprietary medicine for which an exclusive license is provided under the Act, the industry is incentivized to carry out research in order to develop more proprietary drugs for having a competitive edge in the market. This is one of the main differences between the traditional Ayurveda, which was mostly text-based and the industrial

proprietary drugs which are considered to be deviations from the ancient classical texts.

Practice of Trade Secret by Industries

Most of the participants in the study stated that they owned proprietary medicines which were considered their blockbuster drugs (Fig. 1).

In the case of proprietary medicines, the true ingredients of the medicine are to be displayed on the label of medicines. However, an element of secrecy still remains with respect to these medicines which was revealed from the sample study undertaken in the Kerala Ayurveda Industry. However, most of the participants were not open to the question of the use of trade secrets for their products (Fig 2).

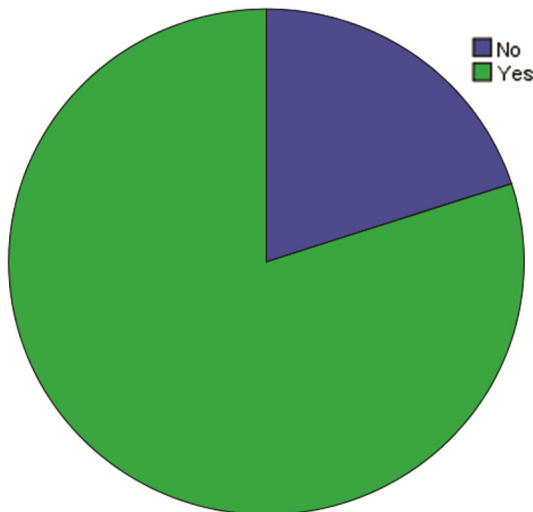


Fig. 1 — Does your company own any proprietary products?

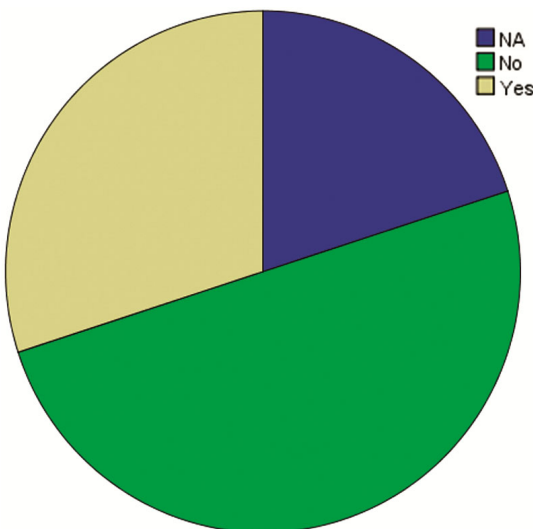


Fig. 2 — Whether any of your proprietary products include secret information?

Many of the participants³⁶ in the study had stated that they owned trademarks (Fig. 3) for their products and few owned patented processes which have already expired. (Fig. 4)

Misappropriation of Trade Secrets

Very few participants clearly stated that they had used certain modes to protect their proprietary formula for preventing its misappropriation by third parties. (Fig. 5)

One such practice was coding of the raw materials used in medicines. Instead of naming the raw materials, certain codes were used to identify the raw materials in order to prevent the people dealing with the manufacture of such medicines from identifying them. The knowledge of the actual raw materials and the ratio in which they were mixed were limited to very few people dealing with manufacture. Those participants³⁷ who had

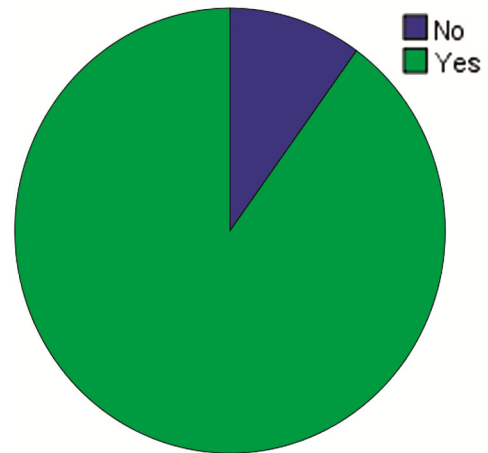


Fig. 3 — Has your company registered any of your brand names as trademarks?

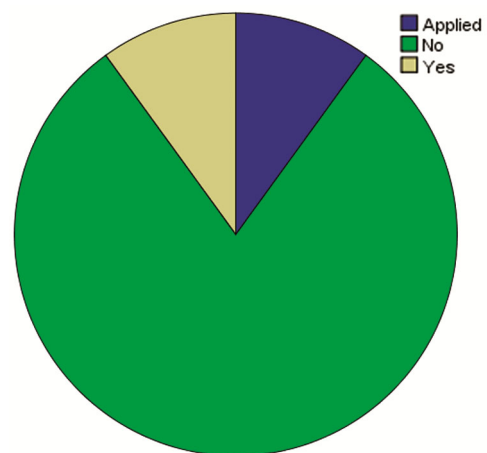


Fig. 4 — Has your company patented any of the products or processes?

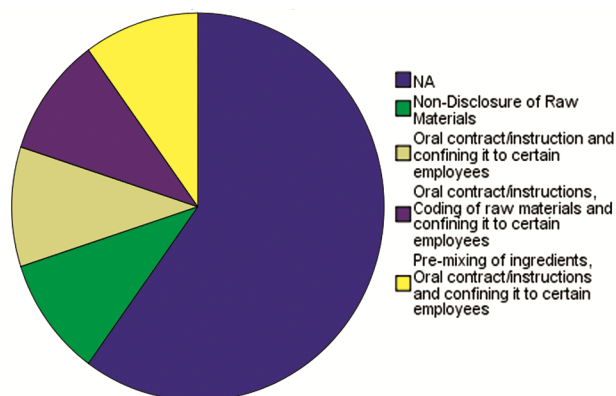


Fig. 5 — What measures have you taken to keep such information secret?

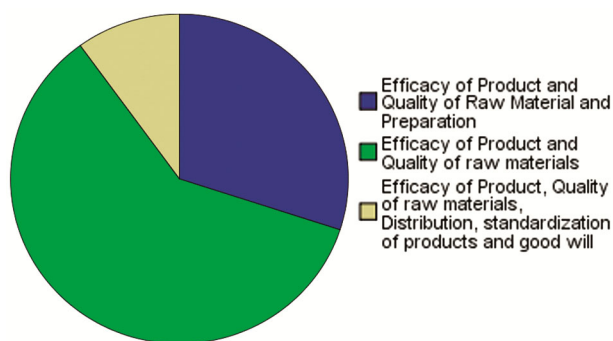


Fig. 6 — What are the measures taken by you to overcome competition in the market?

disclosed that they were using trade secrets stated that there had been instances where their employees had learnt about the ingredients of the medicines and later on engaged in the independent manufacture of the medicines. Most of the participants³⁷ were not bothered about the fact that their employees had misappropriated their secrets and were manufacturing on their own due to various reasons. One of the reasons is the practical difficulty of proving that the employee-developed medicine is a copy of the original one. Minor changes made to the copied ones made it difficult to impose liability on them. The license issued for proprietary drugs was for a specific formula. As long as the persons misappropriating this formula had made changes to it, it was difficult for the owner of proprietary medicines to prove the alleged misappropriation in the court. The protection afforded by proprietary medicines is different from the protection afforded by patents under the Patents Act which provides a wider scope of protection to the patentee. In the majority of the cases, formal confidentiality contracts were not entered into between the employer and employee, and it was based on the relationship of trust.

As per Indian law, in the event of misappropriation of a trade secret, a formal contract was not an essential requirement to initiate a legal claim against the misappropriator.³⁸ If the nature of employment indicated an element of secrecy, the employee had an obligation not to disclose the trade secrets of the employer.³⁸ Hence it is possible to take legal remedies even in such cases, but no cases were initiated.

Another major reason was that the protection provided by the trademark of the drug was good enough to ensure that consumers would not shift to newcomers in the market owing to the trust they placed in the companies of older traditions. In the case of Kottakkal Ayurveda and other large firms, the quality of raw materials, the standardization procedures adopted and the trust placed by people in the brand, played an important role in the strong market presence of the brand (Fig. 6).³⁹

Another surprising reason is the mismatch between the formula submitted before the drug controller and the formula used in the actual manufacturing of medicines by companies. This is where trade secrets play a huge role in preserving the exclusivity of the medicines. Some retired officials⁴⁰ who served in this sector and certain participants⁴¹ disclosed that they were reluctant to disclose the actual formula before the Drug Controller due to the fear that the formula might be leaked to a third party. This is basically due to distrust in the present mechanism or due to ignorance of the law. Hence, they are reluctant to initiate a legal claim against the misappropriator since they themselves have not abided by the law, through proper disclosure of the actual formula used in manufacture of proprietary medicines. In addition, there is a probability that this might be used by individual practitioners in Ayurveda since they are exempted under the law from procuring a license for the preparation of such medicines, provided the medicines are only administered to their own patients and are not used for any other commercial purpose.⁴² There is a need for specific provisions in the Drugs and Cosmetics Act, 1940 in order to protect the trade secret contained in the information submitted before the drug controller for approval. Certain studies have been carried out based on which recommendations have been made in the past for incorporating certain provisions in the Act.⁴³

Reverse Engineering of Proprietary Medicines

Incomplete disclosure of the contents of a drug makes it difficult to manufacture the drug with exact

efficacy and potency. Even if the ingredients are completely disclosed on the label of a drug, while reverse engineering or manufacturing a generic of a proprietary medicine, the difficulty lies in finding the actual ratio in which the ingredients have been mixed while testing it in a lab.⁴⁴ Moreover, the absence of specialized technology unlike the ones seen in the allopathy sector is another major factor that makes reverse engineering of proprietary medicines difficult in the lab. Thus, reverse engineering a proprietary drug that is available on the market is highly expensive. There only lies a possibility of identifying specific substances in a drug that one suspects in the first place.⁴⁵

Findings of Study

The evidence collected from the case studies conducted in the Ayurveda industry reaffirms the prevalence of the use trade secret. Evidently, the existing legal mechanism is hardly relied upon for preventing misappropriation of trade secrets in this sector even though the data from the study showed that there had been instances of where former employees had set up competing businesses by using the confidential information obtained from their previous employment (Fig. 7)

Companies resort to traditional and informal means for preserving secrecy with regard to their proprietary medicines. In any event of misappropriation of trade secrets, they do not initiate any legal action against their employees or third party misappropriators (Fig. 8).

This is partly due to ignorance of the existing legal mechanism and partly due to the fact that such misappropriation of trade secrets has not led to market failure of the products. Other IPs such as trademarks are heavily relied upon for maintaining dominance in the market. As stated earlier the companies also focus on various other factors to ensure that the reputation and goodwill of the products are maintained in the market.

In the Ayurveda industry, confidential information is shared with the employees based on trust and implied oral contracts, which creates a legal obligation for an employee to protect his employer’s trade secrets. The employer can always sue for breach of confidence and breach of contract. However, practices such as entering into non-disclosure agreements, giving proper instructions to employees regarding the nature of the information they are dealing with and the consequences of disclosure of such information to third parties and

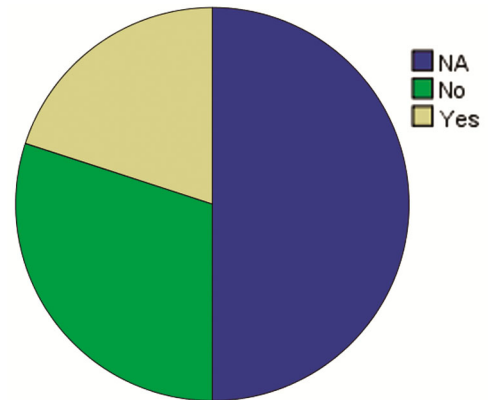


Fig. 7 — Has any of your company’s employee started a similar competing business and produced similar products?

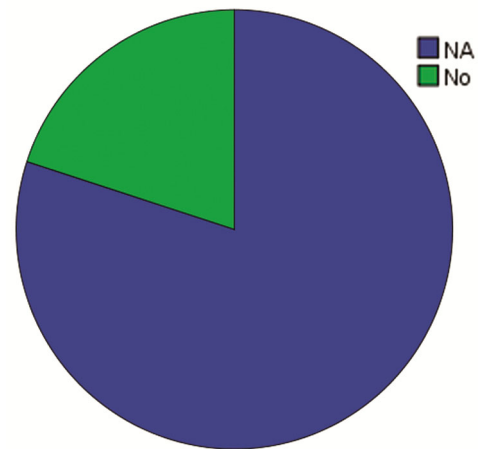


Fig. 8 — If obtained illegally has your company taken any legal measures against such competitor/employee?

competitors, and imposing secrecy measures in their workplace would help an employer in enforcing their trade secrets claims.

The creation of a separate law for furthering the protection of trade secrets would be unnecessary in the present situation where the existing legal mechanism itself is not resorted to for preventing trade secret misappropriation. Instead, it would be better to create awareness about the remedies available under the existing law and adopt strong measures for safeguarding the confidentiality of the proprietary formula submitted before the authorities so as to ensure proper disclosure of the proprietary formula of drugs.

Conclusion

In Ayurveda, while many of the participants were reluctant to admit that they were holding trade secrets, few participants and officials stated that trade secrets

do exist with respect to the raw materials used and processes involved in the manufacture of proprietary medicines. However, it was due to the lack of trust in Government authorities before whom they submit the proprietary formula and data, that they were not very much open about it. As one of the remedies to this grievance, we can adopt the recommendations given under the “Study on test data Protection in India, 2005”,⁴⁶ which had been highlighted in Satwant Reddy Committee Report.⁴⁷ The study suggests provisions to be incorporated in the Drugs and Cosmetics Act, laying down the prohibition and liability for disclosure of data that is considered confidential by the owners of proprietary medicines. It provides the power to the authority to insist on the submission of undisclosed information which forms a part of the proprietary medicine. As quid pro quo, the law also casts liability on any official of the authority for disclosing such confidential information to any third party. As a result, proprietary medicine owners would be more inclined to disclose the actual proprietary formula before the authority in the assurance of a remedy in the event of any misappropriation. Any significant changes brought about in the proprietary formula should be notified and recorded in the register of the authority, failure of which should attract liability under the law in form of a fine and non-availability of remedy in the event of misappropriation of confidential information. The study also gives a recommendation that those submitting data before the authority must clearly specify the confidential information to be protected, and must also certify that it has not been disclosed to anyone and is not available from any other source.⁴⁸ This would contribute to the authenticity of the data so as to ensure that common information already existing in the public domain is not deemed to be protected. As far as remedies are concerned, the applicant submitting confidential information is entitled to an injunction, compensation, and accounts of profits if anyone uses such information in breach of confidence. An important exception that is provided to the provision is that the Government may notify the authority to disclose confidential information on the ground of public interest and must provide terms and conditions for the same.⁴⁶

Participants’ responses show that the misappropriation of trade secrets has taken place but none of them have bothered to pursue any kind of litigation against the misappropriator. One of the reasons can be attributed to the ignorance of the

remedies available under the existing laws, the other reason is the non-aggressive attitude towards their departing employees. Significantly, in cases where a departing employee had set up his own business using the information and knowledge which was studied under his previous employer, there was no instance of market failure. It only leads to further competition in the market. All these companies co-exist in the market now. There are similar examples in the Ayurveda industry, where employees have used the acquired knowledge from their previous employers (usually big players) and have started businesses of their own. The case of Amrita Life Ayurveda Pharmaceuticals is one, which has witnessed employees leaving along with acquired knowledge from them.⁴⁹

The regime for the protection of proprietary medicines of the Ayurveda industry can prove to act as a trade secret registry if properly implemented, a concept left unexplored in the West. The patent or proprietary medicine market is turning out to be a more attractive market, especially with the government lifting the requirements for mandatory clinical trials a few years back.⁵⁰ The industry experience strongly suggests that there is no need for separate legislation. The existing regime if properly administered through Government authorities and properly adjudicated by the courts in India will serve the purpose rather than creating a stringent regime that would curtail the rights of innocent recipients of confidential information.

Empirical evidence shows that even though the industry is actively indulging in trade secrecy, the deployment of the current legal mechanism to safeguard it is very minimal. More studies are required to confirm the need for legislation. For now, evidence suggests that it is not required. It can be safely concluded that companies will innovate and maintain secrecy irrespective of whether there exists a separate trade secret law or not.

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- 43 Proposed amendment to the Drugs and Cosmetics Act, 1946-S.18-A: Prohibition and liability for disclosure of information
- (1) No person shall be entitled to the license under sub-section (s) of Section 10 or under sub-section (s) of Section 18 for a drug unless approved by the licensing authorities in accordance with the Rules prescribed under the Act.
- (2) For the purpose of approval under sub-section (1) the licensing authorities may insist on the submission of any information to be considered as undisclosed by the applicant.
- (3) The licensing 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 sub-section (3) may be liable to be prosecuted under the Official Secrets Act, 1923
- (5) The applicant under sub-section (1) shall be entitled to injunction, compensation or account of profit from any person using the information submitted under sub-section (3) in violation of breach of confidence.
- Amendments to Form 44
Add the following after (2)I(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 anyone. This data is also not publicly available from any other source.
Refer Gopalakrishnan NS & Kadavan B K, Study on testdata protection in India, (Eastern Book Co) 5th Edn. (2005) 47-48.
- 44 Information collected from Veda Herbs & Drugs, Prakkanam, Pathanamthitta and Kallanpally Ayurveda, Koduvayur, Palakkad.
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