

The Foundation Day edition of Lex Orbis Newsletter endeavours to offer analytical insight into two of the contemporary Indian intellectual property right state of affairs. The patent scenario emerging after the rejection of the Novartis's patent application on Gleevec and the Report recommending steps to be taken in the context of Data Protection provisions of TRIPS Agreement will go a long way in establishing the countenance of the Indian Patent Jurisprudence and also the contours of 'unfair commercial use' of the pharmaceutical test-data. This edition also reproduces, previously published, three most widely read articles to commemorate the enterprise of Lex Orbis Group on Research, Publication & Programs.



NEWSLETTER

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Editorial

This is the 10th Foundation Day edition of the LEX ORBIS NEWSLETTER. November 07, 2007 is the 10th Foundation Day of Lex Orbis IP Law Firm. On this occasion, on behalf of the Lex Orbis Family, we extend our sincere thanks to all of you who have supported us in our endeavor to give India an IP Law Firm of global standards. When we started our journey 9 years ago, we were a small team of 6. Today Lex Orbis Law Firm has over 40 attorneys and its associated organizations have close to 150 personnel.

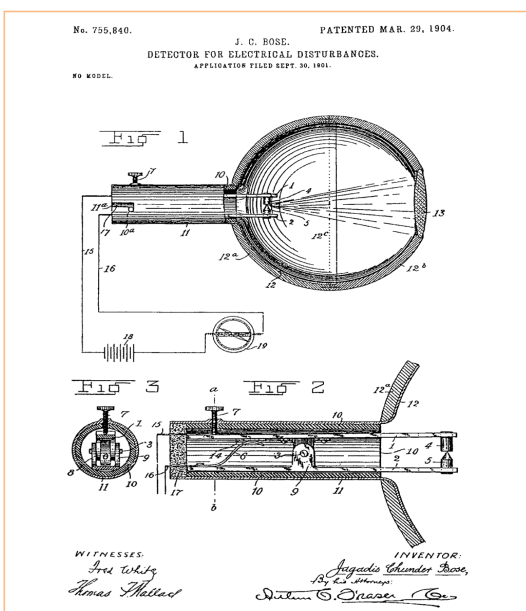
Our in-house Group on Research, Programs and Publications has to its credit 300 articles and 50 public speeches. We continue to create well-researched articles with deep analytical insights on a number of topics concerning Indian Intellectual Property Laws.

The Gleevec cases mark the beginning of the judicial review of the Indian patents law since it was substantially amended pursuant to India's accession to the WTO. The judicial review of the amended legislation has far reaching economic, legal and public policy implications. The Indian courts can help India speed up its journey towards development if they create a progressive national patent jurisprudence. Against this background, we chose to write the lead article for this important special edition on the recent Madras High Court decision on the constitutional validity of Section 3(d) of the Patents Act, 1970 (as amended).

With this edition we are also reproducing the three most widely read articles published by us in past issues of our newsletters. Another important article in this edition covers the recently published report on data protection, a long awaited response by the Indian Government on how to comply with the obligation under Article 39 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

Thank you again for your continued support. We value your comments and feedback. Please send them to mail@lexorbis.com. ■

Group on Research, Publication & Programs (GRPP)
LEX ORBIS IP PRACTICE



Indian Patent Jurisprudence in the Making! - Novartis, *Gleevec*, Section 3(d)'s Constitutional Validity & a Madras High Court's Decision

This article analyses the implication of the decision by the Madras High Court¹ (hereinafter referred to as 'the Court') in *Novartis AG v. Union of India*². The Court dismissed the Writ Petitions³ filed by Novartis seeking to declare Section 3(d)⁴ of the Patents Act, 1970 (as amended) unconstitutional on the grounds that it is TRIPS⁵ non-compliant and violative of Article 14 of the Indian Constitution⁶. The Court considered the following issues:

- (a) Assuming that the amended section is in breach of Article 27 of "TRIPS" and thereby suffers the wise of irrationality and arbitrariness violating Article 14 of the Constitution of India, could the courts in India have jurisdiction to test the validity of the amended section in the backdrop of such alleged violation of "TRIPS"? OR Even if the amended section cannot be struck down by this court for the reasons stated above, cannot this court grant a declaratory relief that the amended section is not in compliance of Article 27 of "TRIPS"?
- (b) If it is held that the courts in India have jurisdiction to go into the above referred-to issue, then is the amended section compatible or non-compatible with Article 27 of "TRIPS"?
- (c) Could the amended section be held to be violative of Article 14 of the Constitution of India on the ground of vagueness, arbitrariness, and conferring un-canalised powers on the Statutory Authority?

The Court declined to address issues (a) and (b). Agreeing with the Respondent's⁷ line of argument, the Court held that it does not have the jurisdiction to decide the validity of the amended Section 3(d) being in violation of Article 27 of "TRIPS". As a corollary to this position, the Court declined to decide whether or not the amended Section 3(d) is compatible with Article 27 of the TRIPS Agreement. The Court's logic in not addressing the issue of Section 3(d)'s TRIPS compatibility was that the WTO system itself provides a mechanism for settling disputes among the contracting parties/Member States. According to the Court, the Dispute Settlement Body of the WTO is the competent and proper forum to decide whether or not Section 3(d) is violative of the TRIPS Agreement and therefore the Court lacks jurisdiction⁸.

This article primarily explores the patent law implications of the Court's reasoning. Therefore, the main enquiry here is to understand if the decision in any way helps the various stakeholders — the patent applicants, the patent attorneys, the patent examiners and the courts— to understand the scope and import of the amended Section 3(d). In that direction, the article tries to determine if the analysis and remarks made by the Court on the amended Section 3(d) can act as a set of guidelines on the type of inventions excluded

(and not excluded) by that section. If the decision offers further clarity on the scope and ambit of Section 3(d), this article considers how that helps streamline the otherwise inconsistent and incoherent patent examination system at the Indian IP Offices.

Before moving on to the above enquiries, let us briefly look at the far reaching policy level implication of the Court's reluctance to review Section 3(d) being in violation of Article 27 of the TRIPS Agreement.

Judicial Review of the amended Patents Law - Keeping "TRIPS" Off

The Court's position is that it lacks jurisdiction to determine if Section 3(d) of the amended Patents Act, 1970, is compliant with Article 27 of the TRIPS Agreement. According to the Court, a municipal court in India has no jurisdiction to review the amendments made to the national Intellectual Property laws with a view to bring them in conformity with the provisions of the TRIPS Agreement. The interpretation of the national law in comparison with the TRIPS Agreement to determine if a particular provision renders the national legislation TRIPS non-compliant is the sole prerogative of the Dispute Settlement Body of the WTO. At another level, the proposition emerging from the Court's decision is that if an international treaty system provides for a dispute resolution mechanism within its framework, then the municipal courts of the contracting states shall have no jurisdiction to adjudicate questions concerning the interpretation of the national legislations amended to fulfill the treaty obligations.

The above propositions raise serious legal, economic and public policy implications. In amending the Patents Act, 1970 to make it TRIPS compliant, the Indian Parliament was faced with the onerous task of crafting provisions to maintain a fine balance between the competing interests of various stakeholders of Intellectual Property Rights. This balancing of interests has resulted in a certain element of ambiguity in some of the amended sections. Many amended provisions permit a range of interpretations, some taking the law very close to, and others far from, the TRIPS Agreement. This inherent ambiguity necessitates judicial intervention. Such judicial intervention cannot be made without giving due regard to the provisions of the TRIPS Agreement and the background considerations that lead to the framing of the TRIPS provisions. Therefore, only a combined patent law, constitutional law, and TRIPS enquiry can yield clarity and finality to the amended sections of the law.

Dissecting Section 3(d)

First let us understand what Novartis's arguments were on



Section 3(d) and its constitutional validity/invalidity. Then let us show how the Respondents argued against Novartis. We will then try to understand the Court's position. Finally, we will see if the Novartis's arguments, the counter arguments by the Respondents, and the Court's formulation based on both offer clarity on the categories of inventions excluded under Section 3(d).

At the centre of the present dispute is Section 3(d). The amended Section 3(d) makes a *"new form of a known substance which does not result in the enhancement of the known efficacy of that substance"* unpatentable. In addition, the Explanation to the Section declares that *salts, esters, ethers, polymorphs, metabolites, pureform, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."*

Novartis argued that the amended Section 3(d) is unconstitutional as it is vague, arbitrary and confers uncanalised powers on the statutory authority (read the Patent Controller). The basis of this argument is that the amended Section 3(d) does not state how to ascertain when there is 'enhancement of the known efficacy of the known substance'. As the Patent Controller has unguided discretion to ascertain if there is an 'enhancement of the known efficacy of a known substance', Novartis argues that

the section is bad in law. Novartis also argued that the Explanation to Section 3(d) is also bereft of any guidelines. According to Novartis the Explanation creates a fiction that deems all derivatives of a substance to be the same as the substance, which may not be the case. Central to Novartis's arguments is the want of clarity of the following phrases used in Section 3(d):

- (a) *"enhancement of the known efficacy"*; and
- (b) *"differing significantly in properties with regard to efficacy"*

Had there been clarity in the Section itself on what constitutes 'enhancement in the known efficacy' of a known substance for its new form to be patentable and what constitutes 'significant difference in properties with regard to efficacy' for a derivative of a substance to become patentable, Novartis would not have been aggrieved. It is important to note that Novartis commenced its legal actions, including the present case, after its patent application was rejected by the Patent Controller, despite the company's efforts to demonstrate 30% higher bio-availability of the (-crystalline form of imatinib mesylate and argue that the claimed invention does not fall within the categories excluded under Section 3(d)⁹. But, Novartis did not offer case studies to show how the Patent Controller can stretch these provisions to reject a large number of pharmaceutical patent applications, nor did the company offer a set of sample guidelines to demonstrate that the above phrases can be

clarified within the legislative framework, failing which there was nothing to constrain the Controller's discretion in rejecting Novartis's patent claims.

The Respondents think it is unwise to fix any specific formula for efficacy, but rather the test under Section 3(d) must remain open-ended. According to the Respondents the amended section provides enough flexibility for the Patent Controller to evaluate the materials placed before him (read patent specification) and arrive at the appropriate decision on whether the new form of a known substance has resulted in the enhancement of the known efficacy of the known substance, or in the case of a derivative, whether it differs significantly from its base form with regard to efficacy for it to become patentable.

Now to the Court's reasoning on Section 3(d). The Court found a definition for the expression 'efficacy' in Darland's Medical Dictionary. The dictionary defined 'efficacy' as the "ability of a drug to produce the desired therapeutic effect". The Court then found that the dictionary meaning of the word 'therapeutic' is "healing of disease - having good effect on the body". Relying on the dictionary definitions of the expressions 'efficacy' and 'therapeutic' the Court offered the following four explanations on Section 3(d).

Explanation 1:

".. if the discovery of a new form of a known substance must be treated as an invention, then the patent applicant should show that the substance so discovered has a better therapeutic effect".

Explanation 2:

"..what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/having good effect on the body?"

Explanation 3:

".. the patent applicant is definitely aware as to what is the "therapeutic effect" of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for".

After giving the above Explanations the Court held that it is a simple exercise for any patent applicant to produce materials showing - what is the therapeutic effect/efficacy of the drug in respect of which a patent is asked for.

On the Explanation to Section 3(d), the Court's observations are as follows:

Explanation 4:

"Therefore in sum and substance what the amended section with the Explanation prescribes is the test to decide whether the discovery is an invention or not is that the patent applicant should show the discovery has resulted in the enhancement of the known efficacy of that substance and if

the discovery is nothing other than the derivative of a known substance, then, it must be shown that the properties in the derivatives differ significantly with regard to efficacy".

The Court's logic was again that it is possible for a patent applicant to demonstrate how a derivative would differ significantly with regard to efficacy from a known substance.

The Court's decision raises the following questions for serious consideration:

Question 1: Do the above explanations and findings, based on the dictionary meaning of the expressions 'therapeutic' and 'efficacy' offer a technically correct understanding of what is excluded as unpatentable under Section 3(d)?

Question 2: Is 'efficacy' as provided under Section 3(d) the same as 'therapeutic effect'?

Question 3: What is the key concern here - the import of the word 'efficacy' or the word 'enhancement' or both?

Question 4: If the word 'enhancement' is equal in importance 'efficacy', does the test under Section 3(d) require determination of the level and degree of enhancement? For example, will 30% enhancement in bioavailability be considered adequate for a new form of a known substance to avoid the 3(d) exclusion?

Question 5: Should emphasis be on the meaning of the word 'efficacy' in the phrase "*differing significantly in properties with regard to efficacy*"? Or are both the expressions 'significant difference' and 'properties with regard to efficacy' of equal importance?

Question 6: What could make the difference in properties with regard to efficacy significant enough to keep the invention outside the ambit of Section 3(d)?

In Conclusion

The enquiry in the present case, as evidenced from these questions, should have proceeded further and offered more technically adequate explanations on what Section 3(d) actually characterizes as unpatentable. Even after this decision, Section 3(d) continues to be an enigma. The Courts are the last resort to fix the gaps in the post TRIPS patent law because the patent office has no examination guidelines. Consequently the patent examination system is very inconsistent. Each Examiner subjectively interprets sections such as 3(d) and issues office actions with claim rejections. Unless and until the courts in India clearly articulate the meaning of various sections in the amended patents law, the law of patents will continue to remain ambiguous and practice uncertain. Section 3(d) is just one example. There are numerous such provisions in the amended act that require close judicial scrutiny. Such judicial review must be technically sound and should form the basis of India's patent jurisprudence. The Novartis case leaves behind an unfinished enquiry. ■

Legislative Updates

1. Copyright Amendments

The Indian Government is planning to introduce a significant amendment to the Copyright Act 1957. A few of the key proposed amendments include:

1. Introduction of Digital Rights Management (DRM)
2. Amendment to Sec. 52(1)(j) on version recordings
3. Introduction of provisions enabling access for persons with visual disability
<http://copyright.gov.in/View%20Comments.pdf>

2. Trade Mark Amendment Act 2007

The Trade Marks (Amendment) Bill 2007, seeking to introduce changes in the present statute to be in conformity with the provisions of Madrid Protocol on International Registration of Marks, was introduced in the Parliament and has been referred to the department related parliamentary Standing Committee on Commerce for examination and report. The Bill seeks to amend the Trade Marks Act, 1999 with a view, inter-alia to -

- (i) prescribe a period of 18 months for the registration of trade marks under Section 23 of the Trade Marks Act, in line with the provisions of the Madrid Protocol;
- (ii) incorporate a new Chapter IVA in the Trade Marks Act containing enabling provisions for accession to Madrid Protocol, including empowering the Registrar of Trade Marks to deal with international applications originating from India as well as those received from the International Bureau (single application with one fee and in one language) and maintain record of international registrations;
- (iii) reduce the time-period of filing a notice of opposition of published applications, from four months to three months, for speedy disposal of proceedings;
- (iv) simplify the law relating to transfer of ownership of trade marks by assignment or transmission and to bring the law generally in tune with international practice and modern business needs;
- (v) omit chapter X of the Trade Marks Act, dealing with special provisions for textile goods, as it has become redundant.
http://www.prsindia.org/docs/bills/1187934649/1187934649_Trade_20Marks.pdf

End Notes

- 1 The High Court of Judicature, Madras, situated in Madras which has been renamed as Chennai.
- 2 W.P. Nos. 24759 and 24760 of 2006 decided on 06.08.2007; Madras High Court.
- 3 There were two Writ Petitions filed by Novartis AG and its Indian subsidiary namely Novartis India Ltd. numbered W.P. No. 24759 of 2006 and W.P. No. 24760 of 2006 respectively. These Writ Petitions were filed under Article 226 of the Constitution of India. The prayer in W.P. N24759/2006 was to issue a writ of declaration that Section 3(d) of the Patents Act, 1970 as substituted by the Patents (Amendment) Act, 2005 is violative of Article 14 of the Constitution and consequently direct the Second Respondent (the Controller General of Patents and Designs) to allow the patent application numbered 1602/MAS/98 filed by the petitioner. In W.P. No. 24760/2006 the prayer was to issue a writ of declaration that Section 3(d) of the Patents Act, 1970 (as amended) is non-compliant with the TRIPS Agreement and that said section is violative of Article 14 of the Constitution of India. However, the petitioner deleted the prayer to direct the Second Respondent (the Controller General of Patents and Designs) to allow the patent application numbered 1602/MAS/98 filed by the petitioner. Therefore the Writ Petition eventually dealt only with the constitutional validity of Section 3(d) on the grounds that it is TRIPS non-compliant and that it violates Article 14 of the Constitution of India.
- 4 Section 3(d) of the Patents Act, 1970 (as amended) reads as follows:
Chapter II: Inventions not patentable.
What are not inventions.- The following are not inventions within the meaning of this Act.-
(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine, or apparatus unless such known process results in a new product or employs at least one new reactant.
Explanation.- For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pureform, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.
- 5 The Agreement on the Trade Related Aspects of Intellectual Property Rights (commonly known as the TRIPS Agreement). Please visit http://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs for the full text of the TRIPS Agreement.
- 6 Article 14. Equality before Law - The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India. Article 14 of the Indian Constitution ensures equality before law including due process of law.
- 7 There were 9 Respondents in all in Writ Petition No. 24760/2006 including the Union of India and the Controller General of Patents and Designs as the 1st and 2nd Respondents respectively. Writ Petition No.24759/2006 had 7 Respondents including the Union of India and the Controller General of Patents and Designs as the 1st and 2nd Respondents respectively.
- 8 The reference here is to the Dispute Settlement Body (DSB) of the World Trade Organization (WTO). For a detailed account on the WTO dispute settlement mechanism please visit http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm#intro
- 9 Novartis AG filed the Indian Patent Application No. 1602/MAS/98 for the invention titled "Crystal Modification of A N-Phenyl-2-Pyrimidlieamine derivative, processes for its manufacture and its use' on July 17, 1998. The application was opposed by generic pharmaceutical companies and the Cancer Patients Aid Association, India. The Patent Controller allowed the oppositions and rejected the application. A key ground relied on by the Patent Controller was Section 3(d).Novartis argued that the (-crystalline form of imatinib mesylate has 30% enhanced bioavailability compared to the free base. It was also argued that crystal form is not an inherent property of imatinib acid addition salt exhibiting polymorphism and human intervention was necessary to produce the (-crystalline form. Therefore, Novartis argued that the claimed invention is not directed at a mere discovery of a new form of a known substance and does not come under the exclusion provided under Section 3(d).

Whither Data Protection

The protection of 'clinical test data' under Article 39.3 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) as intellectual property has always been a debatable issue. The debate has resurfaced again with the Department of Chemicals and Petrochemicals (DCPC) under Ministry of Chemicals and Fertilizers, Government of India coming out with a Report¹ suggesting measures to be adopted in context of clinical test data under Article 39.3. The Department's Report considered:

1. What steps are to be taken in the context of Article 39.3 of the TRIPS Agreement, and
2. Whether data protection can be included in the existing legal provisions or whether a new statute is required.

These two terms of reference were formulated against the backdrop of an absence of separate legislation to protect undisclosed information, i.e., the test-data of drugs and traditional medicines and agricultural chemicals, particularly in light of the need to be TRIPS compliant. Currently test data is submitted to the authorities under the Drugs & Cosmetics Act, 1940 and Insecticides Act, 1968, respectively, for a grant of manufacture and marketing approval.

In its seven chapters, the Report discusses issues related to data protection starting from the minimum legal and regulatory system requirement under Article 39.3, to possible alternatives and the recommendations.

According to the Report, Data Protection is interpreted to include 'Trade Secret' and 'Data Exclusivity' as two forms of protection. The protection under 'Trade Secret', in the Report, covers maintaining the confidentiality of test-data against unauthorized use or disclosure. Unauthorized use or disclosure applies to acts by the Regulatory Authority, while they are permitted to utilize the information to grant marketing approval to subsequent applicants they are not permitted to disclose to others, thus ensuring non-disclosure of the confidential data.

Data Exclusivity as a form of protection, according to the Report, implies non-disclosure as well as non-reliance for a specific period of time. Under such protection the reliance on the data submitted by the Originator to the Regulatory Authority for approving subsequent applications for generic products is not possible.

Opinions varied widely as to the suitability of the form of protection, as well on the other discussed issues pertaining to Data Protection viz. Protection against Disclosure, Protection against Unfair Commercial Use, and New Chemical Entity. Discussions in the report also covered the relevant legal framework and existing statutes. The Drugs & Cosmetics Act, 1940 and the Insecticides Act, 1968 were examined based on their obligation to insist on the submission of test-data for the grant of marketing approval and protection for new drugs and agri-chemicals while

emphasizing the difference in registration data requirements between agro-chemicals and pharmaceuticals.

The Report recommended a three-pronged approach for the protection of the three products considered, viz. Agro-Chemicals, Traditional Medicines, and Pharmaceuticals, due to their different test-data requirements. The Report suggests protecting the test-data (Data Protection) for a fixed period of three and five years for agro-chemicals and traditional medicines, respectively. As regards pharmaceuticals, the recommendation is to have a transition period with higher standards of data protection in the post-transition period, which may include a fixed period of five years for data protection. The 'transition period' is recommended to have "Trade Secret form of Data Protection against unauthorized disclosure and use of proprietary test data (Drug Regulator to continue to place reliance on data of first applicant while approving second and subsequent applicants)". This option is based on the interpretation that data protection is required only against unauthorized disclosure or use of test data, which is sufficient to cover cases of unfair commercial use. Ancillary to this form of protection, the Report recommends that officials in the Office of the Drug Controller General of India be under legal obligation to keep secret the undisclosed information submitted to Drug Regulator for approval of new drugs. The existing legal framework dealing with undisclosed information is in the form of Official Secrets Act.

The recommendation on whether a new statute is required, or whether it is sufficient to bring suitable amendments in the existing legal provision to include data protection, is that there is no need for a separate legislation for data protection. The Drug Regulatory System can be strengthened by implementing minimum standards of data protection through explicit legal provisions in the Drugs & Cosmetics Act, 1940 and the Insecticides Act, 1968 and the Rules framed there under. Such actions ensure that undisclosed test-data of the Originator is not put to unfair commercial use by others.

Comment

Article 39.3 is primarily about protecting undisclosed test-data against "unfair commercial use". Unfair commercial use is meant to prevent the regulatory authority from relying on bioequivalence tests of the Originator while giving approval to subsequent drugs of others. It is not simply about protecting undisclosed test data, which is what is usually inferred. Steps to ensure data protection can also make it possible to disclose the submitted test data securely, but in practice this does not work because generic manufacturers in other countries could always use the disclosed data. Further consideration of this issue compels dissection of the term. Unfair commercial use comprises of two elements, viz. 'unfair' and 'commercial use'. "Unfair" refers to the commercial practices that are 'contrary to honest commercial practices'. The question is then to define "commercial use". What sort of commercial use can be made

of test data? The test data are products of a specific pharmaceutical product having very specific application. To make “commercial use” of test data thus can logically only mean to use the data for the single commercial purpose they can have, which is to support obtaining marketing approval. In other words, governments may not use or rely on test data to which Article 39.3 refers to grant marketing approval to competing products, without the permission of the first registrant (the Originator). This means that governments may not accept mere tests of bioequivalence from the first registrant’s competitors if the first registrant has been obliged to submit complete test data evidencing the efficacy and the non-toxicity of a pharmaceutical product.

The protection of test data against disclosure is an “additional” obligation, the primary being to refrain from facilitating the registration of competing products or the exclusive protection of the contents of data as a condition for obtaining marketing approval. Here the focus is not on trade secret protection but the exclusive protection bargained for. Therefore, article 39.3 actually provides for the exclusive protection of the contents of submitted databases as a condition for obtaining marketing approval.

Conclusion

The prohibition of “unfair commercial use” under Article 39.3 follows a contrario argument that a “fair commercial use” is not precluded. “Fair commercial use” within its ambit takes account of reliance being placed by government on test data developed by the first registrant, which may be the basis for the Report’s recommendation. But to rely on the first registrant’s data to approve a subsequent competitive product is “unfair commercial use”, as it means an unauthorized free riding.

The government, therefore, may ask the applicant to enter into a voluntary agreement with the first registrant in order

to obtain a permission to use those data. Or the government may establish a price to be paid by the applicant to the first registrant. Either of those solutions would avoid repeated clinical trials and yet the data would be protected against unfair commercial use.

On the issue of Official Secrets Act, 1923 being made the legal instrument critical for any proceedings to prosecute any breach of confidence, a key question is whether the protection under the Act is appropriate and adequate for the test data of first registrants. Another point to be debated is whether the Official Secrets Act has built in mechanisms within the meaning of the Act to permit pioneer drug makers to enforce their rights for the proprietary test data.

The jurisprudence on the subject needs more input. The lone case of John Richard Brady² does not throw sufficient light on the topic. By categorizing the facts regarding abuse of technical information, know-how, specifications and drawings as merely a situation for enforcement of general rules of equity and restrain breach of confidence, the focal point of unfair commercial use is lost. Article 39.3 is indeed about a sui generis system of protection of pharmaceutical test databases.

This Report comes out at a moment when, with increasing globalization of the Indian economy, introduction of new products/technology will depend on how Indian law compares with laws of peer competitor nations. Several countries in South-East Asia have data protection for fixed periods. Absence of data protection for certain fixed periods in India may divert the introduction of off-patent products, particularly biotechnological products that have of late become critical in diagnosis and therapy. ■

End Notes

- 1 Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement; 31st May, 2007.
- 2 John Richard Brady versus Chemical Process Equipments P.Ltd. AIR 1987 Delhi 372

News Box

1. A major programme of modernization of the infrastructure of Intellectual Property Offices of India was implemented during the 10th Five Year Plan. With computerization being one of the key components of the modernization initiative, India is now a member of the elite group along with USA, Japan, South Korea, China and the European Patent Office with the launch of the e-filing of Patent & Trademark applications by the Ministry of Commerce and Industry. The e-filing facilities would now enable applicants to file their patent and trademark applications from anywhere in the world at any time and at their convenience through Internet. The State Bank of India has been authorized to receive the payment towards the fees through their Payment Gateway. The National Informatics Centre has developed the modules for the e-filing and will be developing the module for on-line processing. Eventually the complete process of grant of patent or registration of trademarks will be on-line and the Indian Patent and Trademark Office will function almost as a paperless office. E-filing will be achieved in a time span of about two years. The future initiatives are also set in order to make Indian Patent Office (IPO) an International Search Authority (ISA) and an International Preliminary Examining Authority (IPEA) under the Patent Cooperation Treaty.
2. The Government will bring in a legislation by way of ‘India Innovation Act’ to give a fillip to research and innovation and position India as a leader in the 21st century. The India Innovation Act is likely to be modelled on the lines of the ‘America Competes Act’, which focuses on three primary areas of importance to maintain and improve innovation in the US in the 21st century. The three areas are: increasing research investment, strengthening education opportunities in science, technology, engineering, and mathematics from elementary through graduate school, and developing an innovation infrastructure. ■

Reproductions

From the Editors Desk

Lex Orbis is now ten years young, yet we have to cross many milestones. The journey till now reflects, in the writings of Lex Orbis, the growth of intellectual property practice and formation of a firm ground of IP jurisprudence in India. Below we reproduce three widely read articles, each significant now and for the future.

[1] India's Tryst with the TRIPS continues! An Expert Committee reviews the amended Patents Law

Pillai, Manoj; Kumar, Sushil; Kumar, Rajeev; Agarwal, Pallavi.

Preface

First let us look at the politics of TRIPS compliance¹. Then we will look at the legal intricacies involved in India's attempt to read further limitations into the TRIPS². We will then try and see how hard the Committee (entrusted with the task of reading further limitations into the TRIPS) will find its tight rope walk!³ And a final question is whether the Committee's Report will open the Pandora's Box yet again - the Box this time containing all sorts of controversies on pharmaceutical patents!

The politics of TRIPS compliance

It was indeed a hard task for the Indian Commerce Minister to push through the latest amendments to the Patents Act in the Indian Parliament⁴. That was in the month of March 2005, and the Presidential Ordinance of December, 2004 that made the Indian Patents Act TRIPS Compliant had a limited life⁵. The Minister had the hard task of pushing the Bill through (the Patents (Amendment) Bill, 2005) in the face of stiff opposition from the Left Parties, who are known for their anti-patent stands⁶. The task was indeed difficult because the Congress Party to be in power at the Centre required the support of the Left Parties, and the Left Parties oppose WTO/TRIPS norms on patents. Thus the Minister had to make several compromises, some of which lead to interfering with time-tested fundamentals of patents law⁷.

Yet another important compromise the Minister had to make at the Parliament when the Patents Amendments were discussed, was to agree to constitute an Expert Committee to review two contentious issues. These issues are:

- (a) "Whether it would violate the TRIPS Agreement if India excludes 'non-NCE pharmaceutical product inventions' from patentability? and
- (b) Whether it would be TRIPS compatible to exclude micro-organisms from patentable subject matter?

An Expert Committee was appointed by a Government

Notification dated April 06, 2005. The Committee had several sittings and it is now in the process of hearing out the views of various stakeholders. The Notification appointing the Committee did not specify any timeframe for it to make the recommendations to the Government. But, as the Committee comprises of very eminent personalities, a delay in making the recommendations is unlikely.

It is almost certain that the recommendations of the Committee will once again open up a Pandora's Box. The recommendations of the Committee - answering either way the questions referred to it - will definitely lead to yet another heated public debate in India on the social and economic fallout of introducing product patents for food, drug and medicines. This debate frames the latest political background of India's attempt to comply with the obligations under the TRIPS Agreement. India's tryst with the TRIPS Agreement continues.

Deeper Issues

Deeper questions emanate from the legal and technical intricacies surrounding the terms of reference to the Committee. On a preliminary reading, the questions being addressed by the Committee seem to be premised on forgone conclusions. The Committee's enquiry can proceed on two possible lines - the first line of enquiry could be premised on the overriding economic, public health and related social ramifications of India granting patents for 'non-NCE pharmaceutical product inventions' and 'micro-organisms'. Such an attempt to premise the enquiry on the wider economic, public health and related social context may make the Committee's recommendations more controversial in India and less acceptable at the WTO.

The second line of approach could be more legal, thus interpretational. The enquiry can thus traverse through the trajectory of an interpretational process finding room to read limitations in the relevant provisions of the TRIPS

Agreement. The objective of this enquiry would be to make the TRIPS the 'TRIPS Minus'. This line of approach, if adopted with caution and care, may find a higher level of acceptability at the WTO. However, the technical intricacies of this approach may overshadow the efforts to highlight the public health perspectives.

Limiting Patentability to NCEs & NMEs

Does TRIPS permit India (and for that matter any Member Country) to limit patentability only to New Chemical Entities (NCEs) and New Medical Entities (NMEs)?

The Committee will look at the TRIPS and the Indian Patents Act and see if patentability can be limited to New Chemical Entities having one or more therapeutic uses, without violating the TRIPS. In other words, the question is whether it would violate the TRIPS if India excludes a variety of inventions around a New Chemical Entity having one or more therapeutic applications (which the generic drug makers often call as 'perennial patents' leading to "Evergreening"®).

These inventions are typically directed at derivatives of 'new chemical entities' or 'new medical entities'.

The first step in answering this question is to look at what TRIPS originally mandates the WTO Member Countries to provide as against what the Indian patents law (as amended in 2005) provides. The second step in answering this question is to look at if the Doha Declaration on TRIPS & Public Health⁹, the Research Exception Decision (Bolar)¹⁰ and all other "TRIPS Minus" Developments post January 1, 1995 can be used by India as the justification for excluding all 'non-NCE pharmaceutical product inventions' from patentability.

TRIPS Provisions: Article 27(1) of TRIPS provides that '*patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application*'¹¹.

Article 27 of the TRIPS does not allow Member Countries to discriminate patentable and non-patentable inventions on the basis of:
the field of technology;
the place of invention; and
domestic production as against importation.

Article 27 (2) of TRIPS enables Member Countries to exclude inventions, which are necessary to protect human, animal or plant health from the purview of patentability.

The Indian Patents Act, 1970 (as amended) does not limit patentability of pharmaceutical inventions to 'New Chemical Entities' or 'New Medical Entities'. Drafters of the third amendment (the Patents (Amendment) Act, 2005) have attempted to increase the threshold of patentability by setting higher standards of "novelty" and "inventive step"

and by excluding additional categories of subject matters from patentability. For example, the new definition for 'new invention' [Section 2(1)(l)], the amended definition for 'inventive step' [Section 2(1)(ja)], the amended definition for 'pharmaceutical substance' [Section 2(1)(ta)], the addition of a new explanation to Section 3(d) and the expansion of Section 3(d) in general were all aimed at stepping up the threshold of patentability in general.

'Invention' (for purposes of patentability) is defined by the Act to include 'any new and useful product or process involving an inventive step and capable of industrial application'. The new definition of 'new invention' makes the novelty requirement absolute. Novelty of an invention is destroyed if it is anticipated by prior publication, prior public knowledge and/or prior public working anywhere in the world.

The recent amendment also made certain changes to the definition of 'inventive step'. The new definition reads as follows:

"Inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art"

The legislative intent behind this amendment is to increase threshold of the 'inventive step' criterion. But by qualifying the classical definition of 'inventive step' as a feature of an invention that makes it non-obvious to a person of ordinary skill in the art has probably eroded the gravity of the age-old principle.

The amendment also redefined "pharmaceutical substance" as any new entity involving one or more inventive steps. The amended provision did not attach a further limitation that 'pharmaceutical substance' must have at least one new therapeutic application. It is also worth noting that the term 'pharmaceutical substance' is not found anywhere in the body of the Act.

As discussed, the intention in carrying out these amendments was to step up the threshold of patentability. However, this stepping up of the threshold of patentability has stopped short of limiting patentability to NCEs and NMEs. Section 3(d) of the Act contains the most important provision in this regard. The expanded 'Explanation' to 3(d) attempts to exclude a number of subject matters from patentability. However the following subject matters continue to be patentable:

- (a) A new form of a known substance with enhancement of the known efficacy of that substance;
- (b) Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance with significant difference in properties with regard to efficacy.

The Patents Act, 1970 therefore permits patentability of a number of pharmaceutical substances other than New Chemical Entities or New Medical Entities.

What follows from a combined reading of the TRIPS Provisions and the Indian Patents Act is that it will violate the TRIPS Agreement if the Indian Patents law expressly excludes non-NCE pharmaceutical product inventions from patentability. The express violation of the TRIPS Agreement is something that India should avoid, as it could lead to yet another embarrassment at the WTO's dispute settlement process¹².

An alternative line of thinking is to ask the following question - Whether TRIPS Members are free to define the threshold of 'novelty' and 'inventive step' in such a manner to exclude almost everything other than NCEs from the scope of patentability. TRIPS does not mandate Member countries to provide for a certain standard definition of 'novelty' or 'inventive step'. Therefore, it could be possible to require a high degree of "non-obviousness" and connect this high threshold with Section 3(d) to justify the exclusion of non-NCE pharmaceutical inventions from patentability. For example, re-define 3(d) to exclude "any pharmaceutical substance the discovery of which does not involve one or more inventive steps and having no new therapeutic application".

Exclusion of "Microorganisms" from Patentability

The question under consideration is - Whether it would be TRIPS compatible to exclude micro-organisms from patenting?

The relevant provisions of the TRIPS and Indian Patents Act in reference to the issue concerned are as follows:

(a) Article 27(3)(b) of TRIPS mandates Members not to exclude "microorganisms", "non-biological" and "microbiological processes" from the scope of patentability. Thus under Article 27(3)(b) of TRIPS, the Members are under obligation to provide patents for microorganisms.

In order to bring the Indian law in compliance with the aforesaid TRIPS provision, a new clause to Section 3 was added in the Indian Patents Act (by the Patents (Amendment) Act, 2002) which excluded from patentability, plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

Thus TRIPS and the Indian law clearly provide that 'microorganisms' are patentable. As such, it will violate TRIPS if 'microorganisms' per se are excluded from the scope of patentability. The approach, therefore, has to be more 'definitional' and 'interpretative' than a blanket exclusion that attracts yet another dispute at the WTO. The key question that follows is - whether it is possible for India to adopt a very narrow and limited definition of 'microorganisms' to exclude everything other than

"microscopic organisms including ONLY algae, bacteria, fungi, protozoa and viruses." In the alternative, there could be an expansive definition of 'microorganism' to include within its scope all 'biological materials' containing genetic information and capable of reproducing itself or being reproduced in a biological system (as in the European Patent Examination Guidelines¹³).

A pragmatic approach, therefore, is to redefine the enquiry from - Whether it would be TRIPS compatible to exclude 'micro-organisms' from patentability? - to Whether the patentability of 'microorganisms' can be restricted to ONLY algae, bacteria, fungi, protozoa and viruses or - Whether patentability should be extended to DNA fragments, genes, peptide and proteins (as in the Chinese Patent Examination Guidelines¹⁴).

There exists no explicit definition for micro-organisms. Neither the Indian Patents Act nor the TRIPS Agreement define 'micro-organism'. Moreover, no single commonly accepted scientific definition exists. The classical scientific dictionaries define them differently with no consensus. Some definitions are as follows:

a microscopic organism; those of medical interest include bacteria, rickettsia, viruses, fungi, and protozoa¹⁵.

a microscopic plant and animal¹⁶.

an organism which can only be seen with a microscope¹⁷.

In choosing one of the above-mentioned definitional approaches (the one expansive and the other restrictive), one should keep in mind India's Intellectual Property Preparedness in the biotechnology and bio-pharmaceutical sector. Is the Indian R&D globally competitive to make use of a patent system that provides for an expansive definition of 'micro-organisms' that extends to 'biological materials'?

It could be in India's national interest to make 'micro-organisms' patentable and also to provide an expanded definition of 'micro-organism' so as to include in its scope 'biological materials' including DNA fragments, genes, peptides and proteins.

An alternative approach is to adopt the European approach¹⁸ and provide for a further broader definition of "Biological material" to include "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system" and bring that under the scope of patentable subject matter.

An explanation could be added to Section 3(j) with a definition of microorganism (for purposes of determining patentability) as follows:

Explanation - For purposes of this clause, "microorganism" means only microscopic organisms including algae, bacteria, fungi, protozoa, viruses, DNA fragments, genes, peptides and proteins.

In Conclusion

The Committee's deliberations can lead to the following

conclusions:

The exclusion of microorganisms and non-NCE pharmaceutical product inventions from patentability will violate TRIPS. Consequently there should be no further amendments in the Patents Act, and India must maintain status quo. In this line of approach the Committee shall have the limited burden of explaining how a literal interpretation of the TRIPS as against the Patents Act, 1970 does not permit India to exclude microorganisms or inventions other than NCE's from patentability.

The exclusion of microorganisms and non-NCE pharmaceutical product inventions from patentability will not violate TRIPS. Consequently the Patents Act can be further amended to incorporate the additional limitations. This line of approach will place an enormous burden on the Committee to show how it will not violate the TRIPS if India excludes microorganisms and/or non-NCE pharma substances from patentability.

Many IPR-stake holders in India continue to deliberate on a variety of legal and technical issues connected with the Patents Amendment Act, 2005. Addressing most of these issues requires going back to the Parliament for yet another amendment in the Law, which is unlikely to happen in the near future. Further, the terms of reference of the Committee are clear and concise, and that relates to the two questions referred to it. Addressing any additional issue connected with TRIPS compliance amendments to the Patents Act will go beyond the terms of reference of the Committee. It is, therefore, unlikely that the Committee will draw a third conclusion (other than the two mentioned above). ■

End Notes

- In this article the Agreement on the Trade Related Aspects of Intellectual Property Rights is referred to as 'TRIPS' or 'the TRIPS'. For a detailed account of India's recent TRIPS compliance amendments please see: http://www.mondaq.com/i_article.asp_Q_articleid_E_31717
- Please see Basheer, Shamnad M., "India's Tryst with Trips: The Patents (Amendment) Act 2005". The Indian Journal of Law and Technology, Vol. 1, 2005 <http://ssrn.com/abstract=764066>
- The Government of India has appointed an Expert Committee to address two key questions in relation to India's obligations under the TRIPS Agreement. For the full text of the terms of reference of the Committee, please visit www.nic.in/commerce.
- For an opinion on the controversies surrounding the Patents (Amendment) Bill, 2005 please see Abbott, Frederick M., Kapczynski, Amy, and Srinivasan, T. N., Opinion on the Draft Patent Law, <http://www.hinduonnet.com/2005/03/12/stories/2005031201151000.htm>
- Nair, M. D, The fallout of Patents Ordinance, <http://www.hinduonnet.com/thehindu/thscrip/print.pl?file=2005010300621500.htm&date=2005/01/03/&prd=biz&>
- The official position of the Communist Party of India (Marxist) (CPI-M) on patents and India's obligations under the TRIPS Agreement is explained in http://cpim.org/upa/2004_patents.pdf. Also see the Response of the Left Parties to the Note on India's position at the WTO negotiations at http://cpim.org/misc/2005_oct_wto_left.pdf
- The Patents (Amendment) Act, 2005 introduced amendments in the definition of 'inventive step' and 'novelty'. For an account of these amendments please see Pillai, Manoj, The Patents (Amendment) Act, 2005 and TRIPS Compliance - A Critique, Journal of Intellectual Property Rights, Vol 10, May 2005, pp 235-238
- 'Evergreening' refers to patent term extension strategies. For a brief account of the debate on "Evergreening" please see Singh-Nair, Manisha, India: Product Patent Regime & Pharmaceutical Industry In India - The Challenges Ahead, <http://www.mondaq.com/article.asp?articleid=30303&searchresults=1>
- For the text of the Doha Declaration on TRIPS & Public Health please visit http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
- Bolar exception is refers to an exception from the general rules of infringement whereby a generic drug maker is permitted to use patented products, without authorization and prior to the expiry of the patent term, for the purposes of seeking regulatory approval from public health authorities for the marketing of their generic version as soon as the patent expires. For a note on the WTO Panel decision in Canada - Patent Protection for Pharmaceutical Products, please see http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm#exceptions
- For the text of the TRIPS Agreement please visit http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm
- India has a history of losing cases at the WTO Dispute Resolution process. Please see the table of disputes by member countries at http://www.wto.org/english/tratop_e/dispu_e/dispu_by_country_e.htm
- Please see the Examination Guidelines for Biotechnological Inventions at the European Patent Office: http://www.european-patent-office.org/legal/gui_lines/e/c_iv_2a.htm
- SIPO, Patent Protection of New Technologies, http://www.sipo.gov.cn/sipo_English/gfxx/zyhd/t20031225_33947.htm
- Dorland, Dorland's Pocket Medical Dictionary, 1997, Edition 22, P. 416
- Yale, B. A., Webmaster's Encyclopedia unabridged Dictionary of the English Language, 1996, P. 965
- Collin, S., Dictionary of Science and Technology, 2003, P. 395
- European Directive (98/44/EC) of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, 1998 Official J. Eur. Communities O.J. (L 213) 13-21

[2] Case Summary on Trade Secrecy

Not many cases on trade secrets - from a property right perspective

- Research revealed 21 reported cases relating to trade secrets
- Of the 21 cases, 20 related to breach of confidentiality by employees
- At least 1 case each attracted the Information Technology Act, the Indian Penal Code, the Arbitration & Conciliation Act and the Designs Act
- No reported case offers a definition of trade secrets
- At least in 1 case, the Delhi High Court invoked a wider equitable jurisdiction and awarded injunction even in the absence of a contract - John Richard Brady

Indian Cases

- *John Richard Brady And Ors v. Chemical Process Equipments P. Ltd. and Anr* [AIR 1987 Delhi 372]

Issues Considered

- Whether the defendants Fodder Production Unit is based on the plaintiffs' drawings and the related know-how passed to them under the express condition of confidentiality?
- Whether the technical drawings of the defendants are artistic works that qualify for protection under the Copyright laws?

The Court took the position that, even in the absence of an

express confidentiality clause in the contract, confidentiality is implied and that the defendant is liable for breach of the confidentiality obligations.

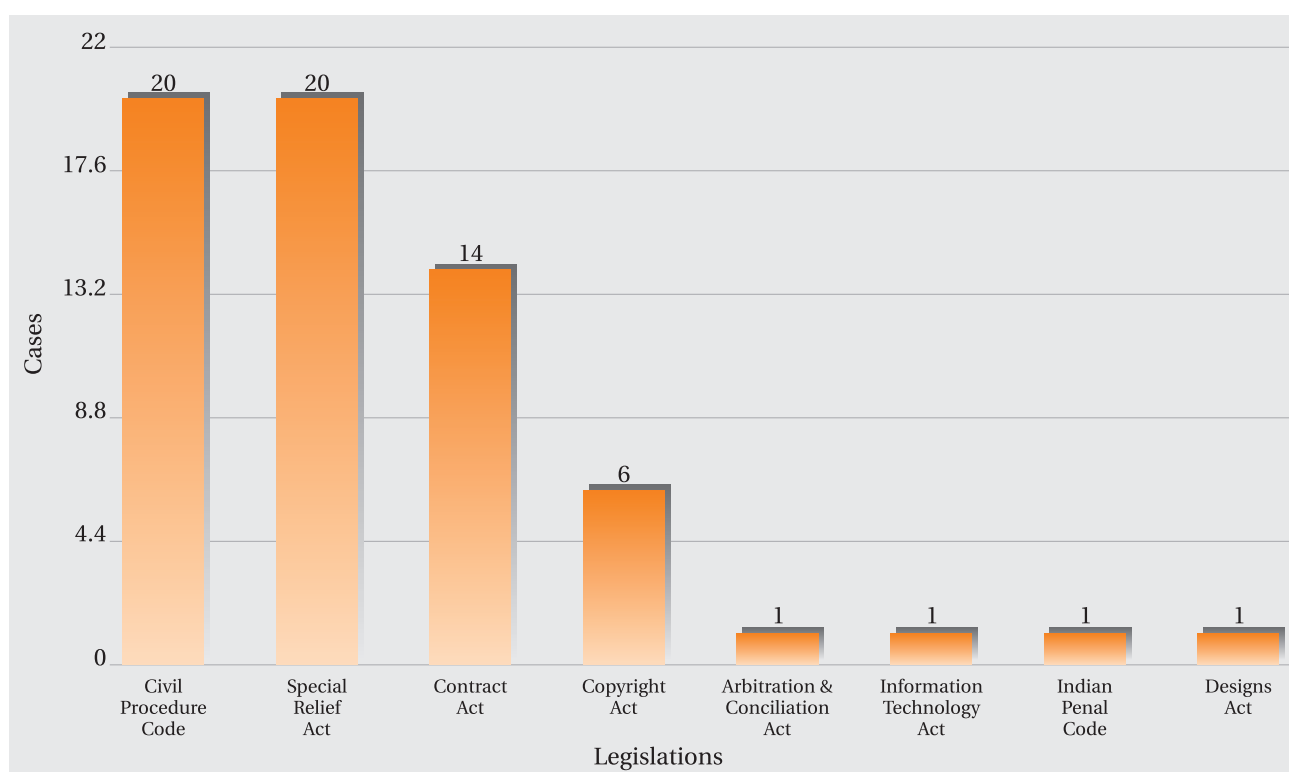
- *Mr. Anil Gupta and Anr. v. Mr. Kunal Dasgupta and Ors* [97(2002) DLT 257]

The plaintiff conceived the idea of 'Swayamvar', a reality television show concerning match making. The plaintiff shared a concept note on this with the defendants. Later on the plaintiff came across a newspaper report informing that the defendants were planning to come out with a big budget reality matchmaking show using the plaintiff's concept. The plaintiff sought injunction.

Issues Considered

- 1) Can there be a copyright in an idea, subject matter, themes, and plots which existed in the public domain?
- 2) Could there be a violation of copyright if the theme is the same as that which existed in the public domain but is presented and treated differently?

Court held that the concept developed and evolved by the plaintiff was the result of the work done by the plaintiff upon the material which may be available in the public domain. However, what made the concept confidential was the fact that the plaintiff had used his brain and thus produced a unique result applying the concept. The Court granted an injunction. ■



[3] Case Reports

Trade Dress: Do You Have One?

Contributed by Lex Orbis

August 08 2005

Introduction

Concept of Trade Dress

Application of Trade Dress

Trade Dress Jurisprudence

Comment

Introduction

Today more than ever before, the value and commercial viability of any business is indubitably tied to its intellectual property. Moreover, intellectual property is increasingly becoming the subject of extensive litigation. For these reasons, it is inevitable that businesses are taking steps to ensure that their commercially important assets are adequately and appropriately protected. Apart from trade names and trademarks, which provide protection against others using the name of a company or its products, there exists another form of protection known as trade dress. 'Trade dress' is legally defined as: *"The arrangement of identifying characteristics or decorations connected with a product, whether by packaging or otherwise, intended to make the source of the product distinguishable from another and to promote its sale."*

However, the law relating to this concept is never simple. To the layman, trade dress is a company's image within the marketplace, and a party can be taken to court if it attempts to present products that look like those of another party but fall short of fraudulently representing the product as that of the other party.

Concept of Trade Dress

Trade dress is a trademark concept. Although it originated in the United States, the law relating to trade dress can be traced to the common law doctrine prohibiting unfair competition. It protects a product's image, encompassing the total image or overall impression created by the product or its packaging. The shape of a shampoo bottle can be trade dress. Similarly, the shape or ornamental features of a chair (its configuration) can constitute trade dress. Even the theme of a restaurant may be considered as trade dress. Thus, in some instances trade dress is reflected in the combination of packaging and labels, while in others it is the product configuration that constitutes the trade dress. Examples of trade dress include the shape of the Coca-Cola bottle, the front grill on the Rolls-Royce car, the shape of a classic Ferrari sports car or the round wall thermostat by Honeywell.

To be registrable as a trademark or a service mark, the elements of the trade dress must be capable of being listed and defined so that the exact parameters of the claimed exclusive right are known. If the combination of

Film Titles Disputed in Passing-Off Action

Contributed by Lex Orbis

July 09 2007

Facts

Decision

Comment

The recent decision in *Kanungo Media (P) Ltd v RGV Film Factory* (2007 (34) PTC 591 (Del)) considered the use of identical titles for two films released at around the same time. In the Indian film industry titles are obtained from regional film trade associations that maintain records and reserve titles at the request of producers. In the present case the Delhi High Court addressed the question of whether the title of a literary work can be protected under the Copyright Act 1957 and, if not, whether trademark principles can be used to protect it.

Facts

Kanungo Media (P) Ltd had adopted the title *Nisshabd* for its Bengali film and had exhibited the film at several film festivals. However, the film was not released publicly. Subsequently, the producer of the film learned that RGV Film Factory had adopted the same title for its forthcoming film in Hindi. Kanungo filed suit for a permanent injunction and copyright infringement and passing off by RGV. Kanungo stated that its film had been shown at many film festivals and had received awards and accolades; thus, it had acquired distinctiveness among the film industry and the public. It further claimed that use of the word '*nisshabd*' or a word deceptively similar to it was bound to cause confusion among the film industry and

Herald of new era for award of damages
Contributed by Lex Orbis

It may be more appropriate to begin with a quote from the judgment of the Delhi High Court in *Time Incorporated v. Lokesh Srivastava & Anr* 2005 (30) PTC 3 (Del). The interesting, equally insightful and self-explanatory extract from the judgment states: "This Court has no hesitation in saying that the time has come when the Courts dealing actions for infringement of trademarks, copyrights, patents, etc. should not only grant compensatory damages but award punitive damages also with a view to discourage and dishearten law breakers who indulge in violations with impunity out of lust for money so that they realize that in case they are caught, they would be liable not only to reimburse the aggrieved party but would be liable to pay punitive damages also, which may spell financial disaster on them"

In the case, apart from granting compensatory damages, the Court also awarded punitive damages of Rs. 5 lacs (US\$ 12,000 approx) as claimed by the plaintiff. The Court stated, "Had it been even higher this Court would not have hesitated in awarding the same". The Court was of the view that the punitive damages should be really punitive and not flea bite and quantum thereof should depend upon the

elements is unique, unusual or unexpected, it can be assumed without evidence that it will automatically be perceived by customers of the goods or services in question as an indication of origin and thus as a trademark. However, if the trade dress is descriptive, inconspicuous or similar to that used by others, it cannot be considered inherently distinctive and can be protected only on proof of secondary meaning or acquired distinctiveness.

The test of deceptive similarity in the case of trade dress is whether there is a likelihood of confusion resulting from the totality of image and impression created by the two trade dresses.

Application of Trade Dress

In light of recent developments in trade and commercial practices, and in order to give effect to important judicial pronouncements, the Indian government felt there was a need for simplification and harmonization of trademark management systems. The Trademarks Act 1999, which came into force in September 2003, attempted to achieve this.

The act protects packages, including any case, box, container, receptacle, vessel, casket, bottle, wrapper, label, band, ticket, reel, frame, capsule, cap, lid, stopper or cork.

In addition, the 'mark' has been defined to include a device, brand, heading, label, ticket, name, signature, word, letter, numeral, shape of goods, packaging or combination of colours, or any combination of these. Therefore, the new definition of 'trademark' in India broadly encompasses almost all elements of trade dress set out under US law.

Trade Dress Jurisprudence

Under the act any distinctive and identifying mark that is capable of distinguishing the goods and services of one owner from those of another may be utilized as a trademark. Such marks are afforded protection under the law.

In addition, a distinguishing trade dress is also considered fully capable of serving as a representation of source. Trade dress is protected under the act only if it is distinctive of the product, thereby representing the origin of the product, or has acquired distinctiveness.

Furthermore, it should have no functional value in relation to the product.

In *RR Oomerbhoy Pvt Ltd v Court Receiver*(1) the Bombay High Court granted an interim injunction in an action for passing off and infringement on the grounds of deceptive similarity. The case concerned a partnership firm, Ahmed Oomerbhoy, which was dissolved due to disputes among the partners. The trademark of the plaintiff's firm, POSTMAN, together with accompanying labels, a logo and a device containing a picture of a postman, was registered in respect of edible oils and was in continuous use for many years. The impugned trademark of the defendant, who was one of the partners of the dissolved

the public, and would imply an association with Kanungo. In addition, Kanungo claimed that the title was aesthetically and philosophically connected with the key theme of the film, and thus it held copyright in the title. Kanungo stated that during the pendency of the suit it had applied for registration of the titles *Nisshabd* and *Nishabd* as trademarks. It argued that it had acquired prior rights over those titles and that subsequent use of an identical or similar title by another party in respect of a film would amount to passing off. It sought relief in the form of a permanent injunction for copyright infringement and passing off, as well as damages and costs. In addition to the suit, Kanungo filed an interlocutory application for an interim injunction.

Kanungo contended that RGV's use of the title was carried out in bad faith. It also alleged that RGV learned of the film title at a film festival where *Nisshabd* was shown, and within a short time of the screening RGV had applied to the Western India Film Producers Association to reserve the similar title *Nishabd*. It further contended that its financial position had prevented it from taking court action earlier, and that it had believed in good faith that once the Central Board of Film Certification had issued a release certificate for its film, it would not grant certification for a film with a similar title to RGV. As soon as Kanungo learned that the board had awarded a release certificate to RGV, it applied to the court for relief.

RGV argued that Kanungo had approached the court in a belated manner as RGV's film had already been completed and was about to be released. RGV also contended that it had

flagrancy of infringement. In *Hero Honda Motors Ltd. V. Shree Assuramji Scooters 2006 (32) PTC 117 (Del)*, the plaintiff claimed token damages and compensation of Rs. 5 lacs and no punitive damages were claimed specifically. Further, the defendant in matter opted not to appear before the Court and the matter proceeded ex-parte. Consequently, no evidence or account of profits could be made before the Court to ascertain the damages. Despite that the Court held that the plaintiff could not be prejudiced by the act of the defendant in staying away from the court proceedings. Rather the defendant must suffer the consequences of damages as set out by the plaintiff. Accordingly, the Court awarded the damages of Rs. 5 lacs as claimed by the Plaintiff.

Another brilliant example of the above trend was exhibited in *Microsoft Corporation v. Yogesh Papat & Anr. 2005 (30) PTC 245 (Del)* where based on the popularity of the plaintiff's software, the Court adopted an assumptive process whereby it calculated financial loss to the plaintiff on assumption of sale of 100 computers each year which the defendant loaded with pirated software. On such assumption the Court arrived at and awarded damages and compensation in the sum of Rs. 19.75 lacs (US \$ 45,000 approx) with interest @ 9% per annum from the date of decree till payment.

firm, was POSTIANO, and was registered in respect of similar products. The design, colour scheme, layout and general visual appearance of the containers and plastic bottles in which the defendant sold oil were almost identical to those of the plaintiff. Furthermore, the products of both parties were sold through the same trade channel.

The court held that:

“The essential feature consisted of the mark POSTMAN printed in red on a blue background with the logo of a postman in yellow and with a thick blue circle around the mark and the logo. The word mark, together with the accompanying device and logo, had a strong association with the products of the partnership firm. The get-up and trade dress were essential aspects of the mark. The use of the mark POSTIANO by the appellant has a striking visual and structural similarity with the mark POSTMAN which was used by the partnership firm. Apart from the use of the word ‘postiano’, the appellant has chosen carefully various other features which would lend a purchaser to associate the product of the appellant with the Postman brand of oil sold by the erstwhile partnership firm.”

The court held that the adoption of the impugned trademark by the defendant was not genuine. In this case, the court recognized the concept of trade dress. In *SVS Oil Mills v SVN Agro-Refineries*(2) the Madras High Court granted an interim injunction for passing off and infringement on the grounds of deceptive similarity. The plaintiff firm manufactured and marketed various kinds of refined edible oils under the registered trademark SVS, with an inverted triangle and a distinctive colour scheme and get-up of red and yellow. The defendant was another firm in the same business that used the same trademark SVS but with a different colour scheme.

In earlier litigation between the parties, the defendant was restrained from using the trademark SVS. Thereafter the defendant changed the mark to SVN but adopted the same colour scheme as the plaintiff. It gave no explanation as to why it changed the colour scheme and get-up of the earlier labels to ones similar to that of the plaintiff. The plaintiff had been using its trading style and trademark continuously for a long period, whereas the defendant entered the field only recently.

The court held that:

“The material form, colour and get-up of the wrapper or label or container of the articles are the physical means of expression and the design of the container or the label is of great significance as it is meant to catch the attention of any purchaser. The design of the label would include not only the trademark, but also the colour scheme and get-up of the wrapper or container as well. It is well known that there are several eye-catching designs and the customers who are familiar with the articles would invariably be guided and attracted to purchase goods by the sight of label. There is a power behind the design of the label as the customers have the intuitive instinct to select the

already invested a large sum in the promotion of the film.

Accordingly, it noted that the delay in filing the suit was fatal since Kanungo had been aware for some time of the adoption of the title and forthcoming release of RGV’s film. RGV claimed that the delay in filing implied that Kanungo consented to the use of its title by RGV and therefore the grant of an injunction could not be justified.

Decision

The Delhi High Court addressed the question of whether the provisions of the Copyright Act could be extended to protect film titles as literary works. The court observed that in the United States, film titles are protected under the Trademark Act rather than the Copyright Act. It held that in India, the legal position in respect of film titles is the same as in the United States. The court observed that film titles fall into two categories: titles of series of film and titles of single copyrighted works. Protection is certain as regards titles of series of film, and such titles enjoy standard trademark protection. However, the court found that in order to extend this protection to the title of a single copyrighted work, it must be proven that such title has acquired a wide reputation among the public and the industry - that is, has acquired secondary meaning. Therefore, in order to obtain an injunction the onus is on the plaintiff to establish that its film title has acquired secondary meaning. The court also addressed the impact of the delay in bringing the suit before the court. Based on the documents on record, the court held that Kanungo was aware of the adoption of the title and the making of the film under that title by RGV.

However, the above trend is not without caution. It is imperative that the assessment of damages has to be based on cogent evidence placed on record. The onus of proving damages as well as the facts that caused the damages is upon the plaintiff who is required to adduce the best evidence in support of his case. The onus is not diluted by the fact that the defendant had not appeared in the matter. In *Indian Performing Right Society Ltd v. Debashis Patnaik & Ors 2007 (34) PTC 201 (Del)* the Court held that the most material evidence which would enable a court to arrive at a fair assessment of the gains that have accrued to a defendant by his infringing acts, would be a true and fair rendition of accounts by the defendant. However, a defendant who is indulging in such illegal activities would obviously not maintain correct accounts and in any case would not place the material in respect thereof before the court. Therefore, it is left to the court to ascertain the probable level of sales of the defendant by other modes. In this case the plaintiff IPRS claimed the compensatory damages of Rs. 1,41,788.57 as the license fee due from the defendant. They further claimed a sum of Rs. 18,58,211.42 as punitive damages. The Court held that claim of punitive damages was grossly disproportionate to the claim of compensatory damages and thus highly excessive. The court found

goods by the design, colour, get-up and the trade name and if the goods of same kind with the same colour scheme and get-up in the labels belonging to two manufacturers with phonetic similarity in trade names are exhibited or offered for sale, a normal consumer of average intelligence with imperfect memory would take one article as belonging to the other."

Therefore, the court held that the adoption of a similar colour scheme and get-up by the defendant would cause confusion and deception in the minds of the general public. From these two cases it is apparent that, under the Trademarks Act 1999, even though there is no specific provision on trade dress action, it is possible to get trade dress protection for products or packaging by filing a suit for passing off or infringement of a trademark. As the law evolves, trade dress jurisprudence is expected to develop further and take more concrete shape.

Comment

Although relatively new in its origin and application, the concept of trade dress has far-reaching implications in determining the commercial success of a business enterprise. Judicious incorporation of the concept into business strategies is not only the key to commercial success, but is also an effective tool to safeguard a company's image and products from any potential infringement.

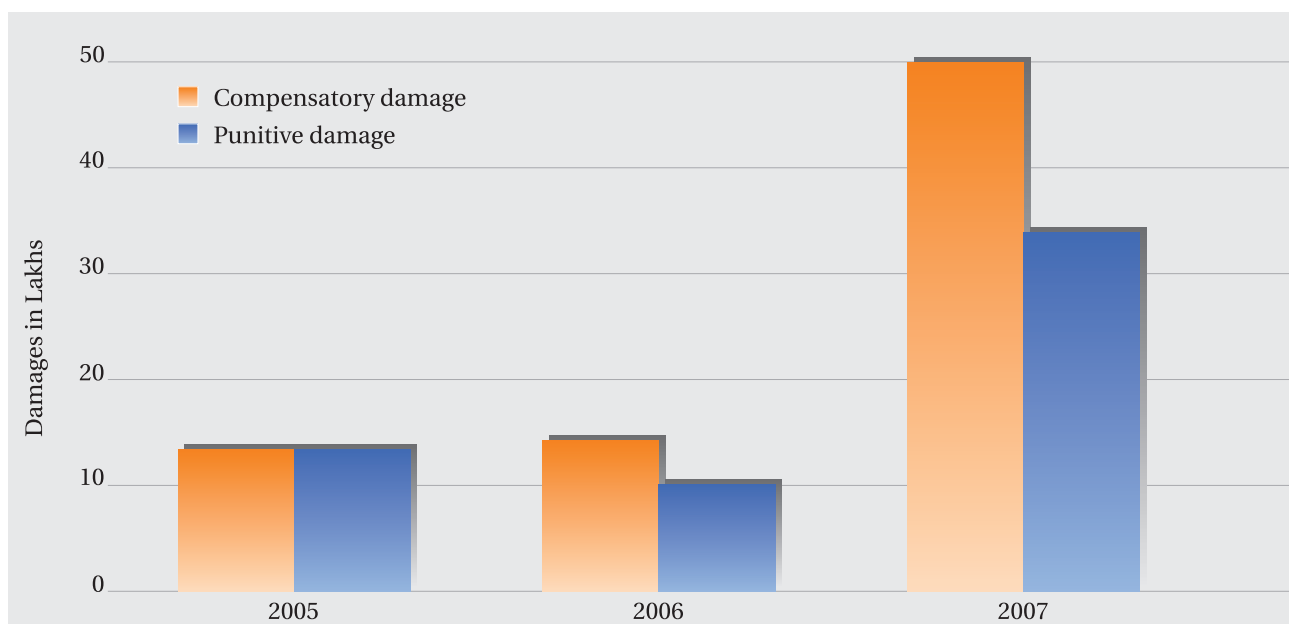
However, Kanungo refrained from legal action and RGV proceeded with the production and release of its film. Kanungo's silence was fatal and amounted to a waiver of its rights. The court also cited the decision in *Ramdev Food Products (P) Ltd v Arvindbhai Rambhai Patel* ((2006) 8 SCC 726), which held that delay in taking action implies acquiescence. Therefore, the court dismissed the suit.

Comment

India faces a lack of judicial precedent in such cases. This case is a commendable attempt by the judiciary to fill the gap. The court's decision reinforces the established position that the title of a copyrighted work cannot on its own enjoy protection under the Copyright Act.

that an award of Rs. 3,00,000.00 as punitive damages to the plaintiff would be fair and justified and being in proximity of double the amount of compensatory damages it cannot be said to be a mere flea bite.

Award of Damages in IP cases



If you have any suggestions, comments or queries, please feel free to email at: mail@lexorbis.com

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