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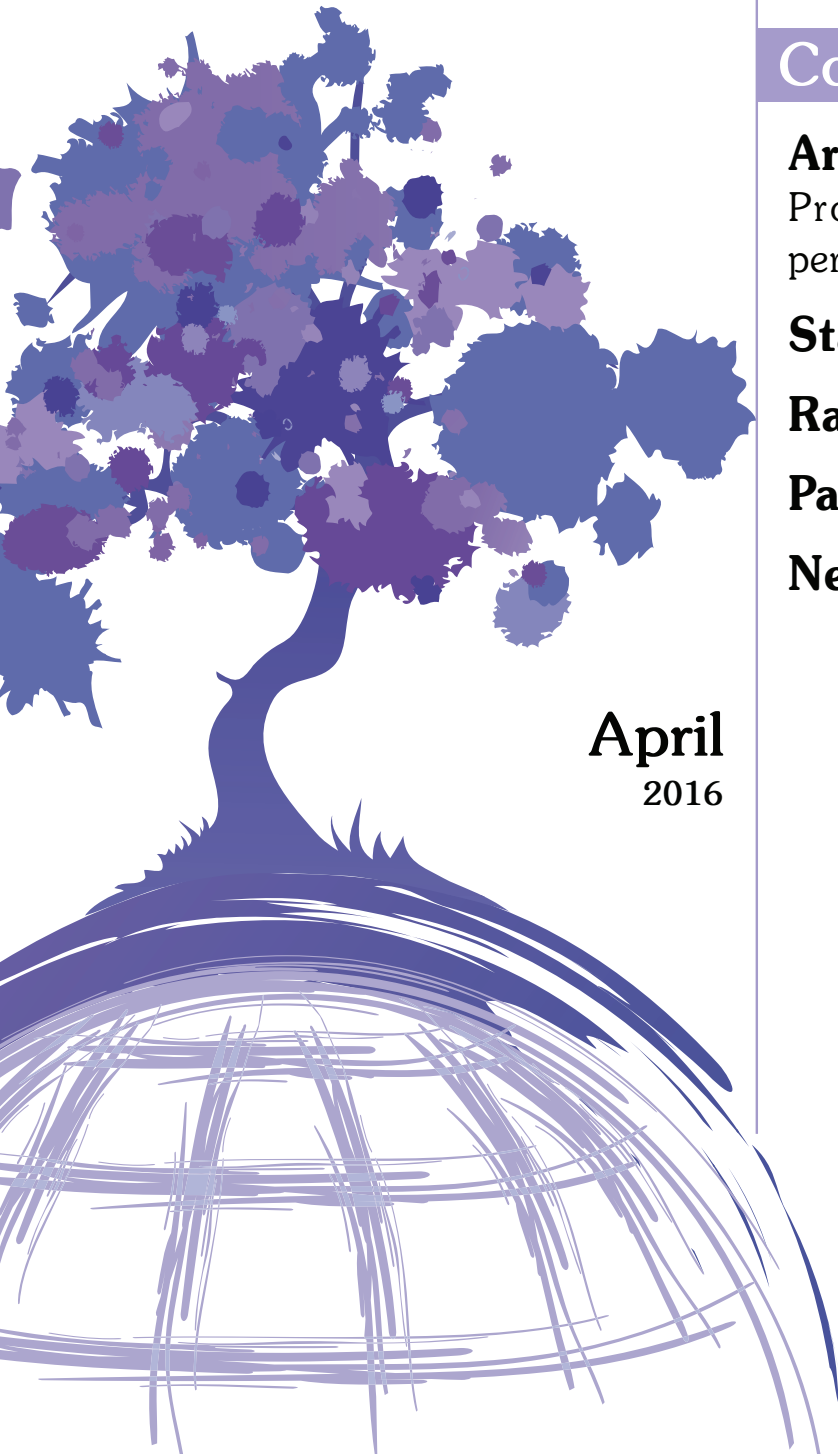
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Article

Product by process claims - A perspective

By **Sribindhu Chivukala & Archana V**

Introduction

Section 2(j) of the Patents Act, 1970 (the Act) defines an invention as a new product or a process involving an inventive step and capable of industrial application. The legal protection to an invention is based on the claims of the granted patent. Typically, a product patent consists of claims defining a structure, apparatus, or a composition. A process patent on the other hand has claims directed towards a method/ process of manufacture of the product. In some cases, the product may not be defined or distinguished from the prior art except by reference to a process by which the product is made. In such cases, the claims define a product in terms of how the product is made; and claims directed to such products are 'product-by-process' claims. For instance, consider a glue stick composition 'X' that is well known in the art. Suppose, a glue stick composition X', with enhanced gluing properties was obtained through a novel and inventive method 'Y', wherein the distinguishing feature between X and X' is not characterizable by any testing parameter. In such cases, a patent for X' obtained through the method 'Y', would be an example of a product-by-process claim. Two important questions that arise in this context are -

1. On application for grant of a patent, how does the patent office evaluate the patentability of an invention for a

- product defined by process claim; and
2. On grant, what determines the fence of such a claim – In other words, under what conditions is a third party considered to have infringed the subject matter disclosed in the product-by-process claim.

This article examines the first question.

Patentability criteria for product by process claims in India

The Indian Patents Act, 1970, and the Manual of Patent Office Practice and Procedure (MPPP) 2011 are rather silent on determining the patentability of inventions covered by a product-by-process claim. However, the Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, issued by the Office of the Controller General of Patents, Designs and Trademarks on 29th Oct, 2014 throw some light on the patentability criteria for examination of a product by process claim, with specific reference to the case of *The Research Foundation of State University of New York v. Asst. Controller General of Patents* (IPAB Order No. 200 of 2012). A brief summary of the case is as follows:

The Research Foundation of State University of New York v. Asst. Controller General of Patents

In this case, the applicant, The Research Foundation of State University of New York

filed a patent application (3219/DELNP/2005) before the Patent Office seeking a patent on ceramic based nanoparticles for entrapping therapeutic agents for photodynamic therapy. The claims of the instant application are directed towards a composite prepared by a novel and an inventive process (product-by-process claims), among other claims. Following the prosecution conducted at the Patent Office, the Controller refused the grant of the patent application under Section 15 of the Act on the ground of lack of an inventive step in light of a prior art document – US 2002/0127224. Aggrieved by the decision of the Controller, the applicant approached the Intellectual Property Appellate Board (IPAB) in appeal against the Controller's decision.

IPAB ruling

Before the IPAB, the applicant argued that since the Controller had acknowledged the process for preparation of the composite as being novel and inventive, the composite prepared by the process was also entitled to be novel and inventive. The IPAB dismissed the applicant's arguments and pointed out that the product-by-process claims must also define a novel and non-obvious product, and that its patentability cannot depend on the novelty and non-obviousness of the process limitations alone. Therefore, the IPAB held that the patentability of a product by process claim

is based on the product itself; and this cannot be conferred by the patentability of the process of preparation of the product in a product by process claim'.¹

In the present case, the IPAB observed that the difference between the composite of the instant invention and that of the prior art was with respect to a carrier used for drug delivery, both of which are non-biodegradable. The IPAB further noted that the composite of the instant application does not have any enhanced effect over that of the cited prior art. In the absence of any comparative advantages, the IPAB upheld the Controller's decision for refusal of the claims directed to the composite.

Umicore AG & Co.KG v. Controller General of Patents

In another case pertaining to product by process claims, the applicant, Umicore AG & Co.KG, filed a patent application (1476/KOLNP/2009) before the Patent Office seeking a patent for a Vanadium free catalyst obtained by a process of impregnating Ce-Zr mixed oxide with an aqueous solution of a compound of Cr, Mo, W, or a mixture thereof, whereby the vanadium free catalyst obtained by this process has better catalytic properties. During examination of the patent application, the controller objected to the claims of the instant application for lack of novelty in light of a prior art (EP1736232) that discloses a

¹ IPAB order 200/2012

vanadium free catalyst prepared by a different process. In light of the cited prior art, the Controller pointed out that the product cannot be rendered novel merely by the fact that it is obtained by a different process. To overcome this objection, the applicant submitted that the claimed process is different leading to a novel product not known in the art. The applicant submitted that the different process employed by the applicant resulted in a catalyst having W inside the pores of the Ce-Zr mixed oxide, unlike that of the prior art, where the W is not located inside the pores; but is incorporated into the oxide structure as Ce-W-Zr oxide. The applicant further compared the catalytic properties of the product of the instant application with that of the prior art, by way of examples, to prove its enhanced catalytic activity, and free flowing properties. The applicant further contented that the different properties are a clear hint that both the products are not the same, but are different; and that the difference lies in the mode of preparation of two catalysts. In light of this argument, the Controller proceeded to grant the patent.

The key take away from the above decisions is that when a product is defined by its method of manufacture; the question to be answered is whether the product under consideration is identical to the known products. The burden of proof for allegedly distinguishing the product in a 'product-by-process' claim from that of the prior art product lies with the applicant. The applicant has to provide experimental

evidence that the modification of the process parameters results in an altogether new product, for example, by showing the distinct differences in the structural properties of the claimed product versus the known product.

Patentability criteria for product by process claims in US & EU

The jurisprudence with regard to product by process claims are well established in other jurisdictions such as the Europe and the US. The EPO allows claims for products defined in terms of a process of manufacture only if the products as such fulfil the requirements for patentability, i.e. *inter alia* that they are new and inventive and if there is no other way of clearly defining the product. A product is not rendered novel merely by the fact that it is produced by means of a new process. [*T 0081/14, Kennametal Inc. v. Mitsubishi Materials Corporation*].

Similarly, the position of law in the US with respect to product by process claims is that the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious in light of a product in the prior art, the claim is not patentable even though the prior product was made by a different process. [*In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)*]

The two Indian cases discussed above seem to echo similar positions as in the US & EU.

[The authors are Senior Patent Analysts, IPR Practice, Lakshmikumaran & Sridharan, New Delhi]

Statutory Updates

Trade Marks Registry keeps abandonment orders in abeyance

The Trade Marks Registry had taken steps to treat as abandoned, applications in which no reply had been received even after they were communicated to the applicants and authorized agents. Following complaints of non-receipt of examination report from TM Registry or reply having been duly filed, and filing of writ petition before High Court of Delhi, the Trade Marks Registry has issued Public Notice dated 11-4-2016 notifying the public that abandonment orders passed by the Registrar of Trade Marks after 20/03/2016 are being kept in abeyance. The applicants or their authorised agents concerned can file the reply to examination reports containing office objections either through the E-filing services of

trademarks available at the official website. As per the earlier Public Notice dated 4-4-2016, those who sought to make representations and reply to examination reports were directed to do so by 30-4-2016.

First Statement of Objections (FERs) to be issued electronically

By Office Order No. 23/2016 dated 31-3-2016, it has been intimated that an auto-allotment system would be implemented from 1-4-2016. The FERs would be communicated to the agents /applicants by respective Controllers only through e-mails. The first examination report would be available on the official website InPASS. Responses to the FERs can be filed through the comprehensive e-filing system or through the respective front office counter.

Ratio Decidendi

Trademarks - Ex-parte ad-interim injunction possible only in case of inherently distinctive mark

Division Bench of the Delhi High Court has vacated the *ex-parte ad-interim* injunction granted by the Single Judge Bench against a major mobile and personal computer manufacturer, for use of words 'Split View'. The Court in this regard held that the issue for consideration was whether 'Split View' is descriptive of an essential feature of the computer programme thereby rendering the words, even if used in conjunction with each other, not eligible to be a trade mark.

It was observed that firstly it has to be tested that respondent's trademark 'SplitView' is inherently distinctive or has assumed secondary distinctiveness, and thereafter it has to be evaluated whether use by the manufacturer is truly descriptive and in conjunction with a trademark for the consumer to know the difference between descriptive use and trademark use.

While requesting the Single Judge to hear arguments in the application seeking interim injunction pending disposal of the suit filed by the respondents, the Court observed that an *ex-parte ad-interim* injunction in a matter

concerning trademark violation should ensue only if a very strong *prima-facie* case is made out with respect to a trade mark which is inherently distinctive. The mobile and PC manufacturer, in the case, contended that people in the field of computer software programming used the words ‘Split View’ to describe an essential feature of the function of the software programme. Citing some examples, the manufacturer here also argued that the consumer recognizes that descriptive words are used by them to describe the essential functionality of its product and not the product, and that those non-descriptive words are used by them as the name of the product. [Apple Inc. v. Rohit Singh – Judgment dated 7-4-2016 in FAO (OS) Comm. 11/2016, Delhi High Court]

Copyrights – Interim injunction cannot be granted on cursory material

Bombay High Court has refused to grant *ad-interim* relief in a case of alleged copying of Plaintiff’s registered literary work (script of a movie) without his permission, license or assignment. The Court in this regard noted that, it was not known as to whether the Plaintiff merely ‘pitched’ the concept or narrated the entire script to the respondent. Further, noting that there was absence of evidence of any follow-up action, or record of any such delivery, the Court held that it was not possible to grant the *ad-interim* relief on the extremely cursory material. Delay in moving the court, inasmuch as the Petitioner waited virtually till the eve of the release of the film, was also found to be

not satisfactorily explained, while the Court held that the application was an intolerable and unacceptable imposition on judicial time. [Mahesh Vaijnathrao Doijode v. Yashraj Films Private Ltd. – Order dated 11-4-2016 in Notice of Motion (L) No. 1153/2016 in Suit (L) No. 343/2016, Bombay High Court]

Copyright in drawing and sketches for dresses, not registered as design – Delhi HC clarifies ‘capable of being registered’

Delhi High Court has declined to grant injunction against infringement of copyright in drawings and sketches for dresses when the dresses were created more than 50 times using said design which was not registered under Designs Act. Plaintiff’s contention that once copyright artistic work is excluded from the definition of a design under Section 2(d) of the Designs Act, Section 15(2) of the Indian Copyright Act does not come into play, was rejected by the Court. Considering the phrase ‘capable of being registered’ in Section 15(2), it was held that a drawing or a sketch or a design need not necessarily fall within the definition of design under the Designs Act to be covered under Section 15(2) of the Indian Copyright Act. The said phrase was found to mean that there is possibility of a copyrighted sketch or drawing or artistic work being also capable of being registered as a design though excluded from the definition of design. Division Bench decision of the Court in the case of *Microfibres Inc. v. Girdhar & Co.* was relied by the Court while it distinguished decisions in the cases of *Midas Hygiene Industries Pvt. Ltd.* and

Rajesh Masrani. [Ritika Private Limited v. Biba Apparels Private Limited – Judgment dated 23-3-2016 in CS(OS) No.182/2011, Delhi High Court]

Assignment/license of copyright should be in writing to be valid

Emphasising that an entitlement of copyright can only be by an agreement in writing signed by the parties, the High Court of Delhi dismissed the suit brought by the plaintiff for suit for declaration, injunction and rendition of accounts. On the strength of a letter signed by the publisher/copyright holder by which

the plaintiff was permitted to reprint third edition of a title, the plaintiff sought to assert his rights over a special edition brought out by him. He did not implead the original owner of the copyright despite being directed to do so. The High Court held that to be valid, an assignment/license has to be in writing and signed by the owner and also since the owner was not party to the proceedings, it dismissed the suit. [*K.M Verghese (Deceased) through LRs v. CBS Publishers and Distributors, CS(OS) No.567/2009, Judgement dated 7-4-2016, Delhi High Court*]

Patent Office Decision

No patent for numbering device – Section 3(b) invoked

Indian patent Office at New Delhi has refused to grant patent in an application titled ‘Method and device for controlling the position of the numbering wheels of a numbering device’. The Assistant Controller Patents & Designs was of the view that there was a contravention of Section 3(b) of the Patents Act, 1970 inasmuch as the primary or intended use or commercial exploitation of the invention, used in printing presses for carrying out numbering of printed documents, especially bank notes and the like securities, could be contrary to public order or morality. The patent office in this regard noted that printing of bank notes is sensitive matter, is an area lawfully banned and is the prerogative of the State. The patent office refused to comment upon the patents granted in the related field. [*Kba-Notasys SA – Order dated*

7-4-2016 in the Matter of Patent Application No. 1375/DELNP/2009]

Method to shield eyes with insufficient pigmentation by surgical intervention not patentable

The Controller held that a claimed method relating to modifying eye color is in contravention to Section 3(i) of the Indian Patents Act, as the method involves surgical intervention by a person of specialized skill, thus being a ‘surgical’ process essentially. It was further observed by Controller that the claim attracted the provisions of Section 3(i) as being a prophylactic method as, by the own admissions of the agent for the applicant, the claimed method is a preventive method to shield eyes with insufficient pigmentation from harmful radiation. Though processes, outcome of which are purely cosmetic in nature, such as the method of this instant case, are generally

outside the ambit of Section 3(i), the refusal hints that necessary intervention by a person of a specialized skill, regardless of outcome, would attract the provisions of Section 3(i),

thus further limiting the general exclusion of cosmetic methods. [Order of the Assistant Controller of Patents dated 14-3-2016 in patent application no. 1376/DELNP/2007]

News Nuggets

Another stumbling block for personalized medicine?

Personalized medicine as the name suggests strives to provide individualized diagnosis and treatment regiment, which is likely to be more effective. However, in a recent judgment by the United States Court of Appeals for the Federal Circuit in *Genetic Technologies Limited v. Merial LLC, Bristol-Myers Squibb Company* (decided April 8, 2016), the Federal Circuit held that Claim 1 in US patent No. 5,612,179 does not satisfy 35 U.S.C. § 101 on the ground that the claim is simply a recitation of a law of

nature. In essence, the Claim 1 of the patent in question was directed to detection of a coding region of an allele by amplifying non-coding region which is in genetic linkage with the coding region. This decision closely mirrors the thought process of the Federal Circuits Court in the decision of *Ariosa Diagnostics Inc. v. Sequenom, Inc.*, where method of detection of paternal DNA in maternal blood was invalidated, and such similar landmark decisions as in *Association for Molecular Pathology v. Myriad Genetics* (US Supreme Court), and *Mayo v. Prometheus* (US Supreme Court).

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