Novartis Ag v. Union of India, (2013) 6 SCC 1

Intellectual Property

Patents

Ss. 3(d) r/w Expln., 2(1)(j) & (ja) and 83 - Known substance - New form of - Patentability/Patent protection to new form of known/existing medicine/pharmaceutical product - (1) Invention Test, and (2) Enhanced Therapeutic Efficacy Test - Cumulative applicability of - Opinion of experts/Published research in reputed journals - Relevance of - Non-availability/non-adducement of research/empirical data to establish enhanced therapeutic efficacy - Effect of - ``Evergreening'' - Prevention of - Form/product/salt which is actually marketed (including claims/declarations made on packaging) vis--vis subject form/product/salt - Deceptive patent claim - Inference of - When warranted - Gleevec/Glivec, a cancer inhibiting medicine manufactured by appellant - Denial of patent in India - Grounds - Obviousness - Lack of novelty - Anticipation from prior art - No enhanced efficacy over known substance - Held, Imatinib Mesylate was a ``known substance'' from US Patent Zimmermann Patent No. 5,521,184 (1996) and further, appellant could not establish that b-crystalline-Imatinib Mesylate (``b-IM'', for short) had any enhanced therapeutic efficacy over Imatinib Mesylate - Thus, Gleevec/Glivec/b-IM did not at all qualify for an Indian patent - Indian Patent Law supports only really deserving patents in pharmaceuticals and discourages evergreening, as amended portion of S. 3(d) sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to permit patents for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of patent term on spurious grounds - To satisfy Invention Test in respect of subject product i.e. b-IM in respect of which Indian patent was sought, appellant claimed that by two-stage invention, they first invented ``Imatinib Mesylate'' from ``Imatinib'' (a derivative compound of N-phenyl-2-pyrimidine-amine) invented by Dr J?rg Zimmermann and patented in Europe, and in United States under Zimmermann Patent No. 5,521,184 - That, they then invented b-crystalline-Imatinib Mesylate (b-IM) from Imatinib Mesylate - To satisfy Enhanced Therapeutic Efficacy Test, appellant claimed that ordinary Imatinib Mesylate was converted into a-crystalline and b-crystalline forms - That conversion of ordinary salt into b-crystals, rendered drug more effective as b-IM salt had better absorbability and was relatively more stable, in addition to other enhanced physico-chemical properties such as more solubility, less hygroscopicity, and had enhanced bioavailability, all of which rendered the new form i.e. b-IM a more effective medicine - ``Imatinib'' itself was a disclosed substance under Zimmermann Patent No. 5,521,184 - Further, Zimmermann Patent No. 5,521,184 had the teaching for making of ``Imatinib Mesylate'' from ``Imatinib'', and for its use in pharmacological compositions - Appellant applied for and obtained patents for many forms of Imatinib (including its b and a-crystalline forms), but never applied for any separate patent for non-crystalline Imatinib Mesylate as appellant always maintained that Imatinib Mesylate is fully a part of Zimmermann Patent No. 5,521,184 - Furthermore, US Board of Patent Appeals while granting US Patent Zimmermann Patent No. 6,894,051 B1 to appellant for b-IM had also proceeded on basis that Zimmermann Patent No. 5,521,184 had the teaching for making of ``Imatinib Mesylate'' from ``Imatinib'' - Appellant, held, is bound by this finding recorded in its own case - Hence considering all of the above, held, ``Imatinib Mesylate'' was a known substance under Zimmermann Patent No. 5,521,184 - Question whether b-IM involved an ``inventive step'' not gone into - Even assuming that b-IM is new in the sense that it is not known from Zimmermann Patent No. 5,521,184, enhanced physico-chemical properties of b-IM i.e. (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, and enhanced bioavailability, though otherwise beneficial did not of themselves establish enhanced therapeutic efficacy (which must be judged strictly and narrowly) of b-IM vis--vis known substance Imatinib/Imatinib Mesylate - Whether or not enhanced physico-chemical properties/bioavailability of b-IM over Imatinib Mesylate/Imatinib-in-free-base-form led to an enhancement of therapeutic efficacy, held, had to be specifically claimed and established by research/empirical data which was not done in the present case - In fact, there were clear and unambiguous averments in subject Indian patent application of appellant that all therapeutic qualities/pharmacological properties of b-crystalline-Imatinib Mesylate were also possessed by Imatinib-in-free-base-form or its salts (see also Shortnote F for detailed ruling on test of enhanced therapeutic efficacy) - Lastly, the drug Gleevec as marketed in India (as also in United States), on its package was described as ``Imatinib Mesylate tablets 100 mg'' with no reference to b-IM - Hence, claim for patent for b-IM was an attempt to obtain patent for ``Imatinib Mesylate'' which would otherwise be impermissible - Thus, held, subject product b-crystalline-Imatinib Mesylate failed to qualify both test of invention and test of enhanced efficacy/patentability as laid down under Ss. 2(1)(j) & (ja) and S. 3(d), (2013) 6 SCC 1-A

Intellectual Property

Patents

Ss. 2(1)(j), (ja) and 3(d) & Expln. - Known substance - New form of - Patentability/Patent protection to new form of known chemical substance/pharmaceutical product - Cumulatively applicable qualifying tests: (1) Test of Invention, and (2) Test of Enhanced Efficacy - Chemical substance/pharmaceutical product which is a new form of a known substance with known efficacy, held, must pass in addition to test of invention given in Ss. 2(1)(j) and (ja), test of enhanced efficacy as prescribed in S. 3(d) r/w Expln. thereto, (2013) 6 SCC 1-B

Intellectual Property

Patents

S. 2(1)(j) r/w Ss. 2(1)(ac) & 2(1)(ja) and S. 3 - ``New product'' - Meaning of ``new product'' in the context of chemical substances and pharmaceutical products, explained - Held, a new product in chemicals and especially pharmaceuticals may not necessarily mean something altogether new or completely unfamiliar or strange or not existing before - It may mean something ``different from a recent previous'' product or a product ``regarded as better than what went before'' or a product which is ``in addition to another or others of the same kind'' - However such ``new'' chemical/pharmaceutical would have to qualify tests of invention and enhanced efficacy to qualify for patent protection (see Shortnotes A, B and F), (2013) 6 SCC 1-C

Intellectual Property

Patents

Ss. 3(d), 2(1)(ja) and 64(1)(e) & (f) - Expression ``known'' under S. 3(d) - Scope of - Relevance of meaning of ``publicly known'' in S. 64(1)(e) & (f) - Obviousness to person skilled in the art - Held, to satisfy the requirement of being ``known'' in S. 3(d) it is not necessary that it should be widely used to knowledge of consumer public - It is sufficient if it is known to persons who are engaged in pursuit of knowledge of the patented product or process as persons skilled in the art, either as men of science or as men of commerce or as consumers, (2013) 6 SCC 1-D

Intellectual Property

Patents

S. 3(d) r/w Expln. thereto - Known substance - New form of - Patentability/Patent protection - Test of enhanced efficacy prescribed in S. 3(d) r/w Expln. thereto - ``Efficacy'' - Meaning of - Held, efficacy means ``ability to produce a desired or intended result'' - Test of efficacy in each case would depend upon the function, utility or purpose of product under consideration, (2013) 6 SCC 1-E

Intellectual Property

Patents

S. 3(d) r/w Expln. thereto - Known/existing medicine/pharmaceutical - New form of - Patentability/Patent protection - Test of enhanced efficacy - Applicability - Meaning of ``efficacy'' in case of medicines/pharmaceuticals, held, is ``therapeutic efficacy'' - Enhancement of therapeutic efficacy of existing/known medicine by discovery of new form - Determination of - Opinion of experts/Published research in reputed journals - Relevance of - Empirical/research data - Role of - Physico-chemical properties and bioavailability of the new form - Enhancement in - Effect of - Therapeutic efficacy of a medicine, held, depends on whether it has the desired effect in curing of disease for which it is prescribed - Therapeutic efficacy of a medicine must be judged strictly and narrowly - Expln. to S. 3(d) indicates what is not to be considered as ``therapeutic efficacy'' - Physico-chemical properties like better flow, thermodynamic stability and lower hygroscopicity of the new form, held, do not automatically lead to inference of better therapeutic efficacy of the new form - Further, increased bioavailability by itself may not necessarily lead to an enhancement of therapeutic efficacy - Therapeutic efficacy has to be established with reference to research/empirical data, whether it be attributable to physico-chemical properties, bioavailability or any other property/feature of medicine/salt in question - b-crystalline-Imatinib Mesylate (b-IM) - Held, innovation of b-crystalline form i.e. b-IM with enhanced physico-chemical properties, but without any research evidence to as to enhanced therapeutic efficacy, not sufficient to afford patent protection to new formulation b-IM of old drug, (2013) 6 SCC 1-F

Intellectual Property

Patents

S. 3(d) r/w Expln. thereto - Known substance - New form of - Patentability/Patent protection - Enhancement of efficacy of existing/known substance by discovery of new form - Determination of - Properties/Features of the new form - Relevance of - Opinion of experts/Published research in reputed journals - Relevance of - Empirical/research data - Role of - Held, only such of the properties/features of the new form that directly relate to enhancing its efficacy are relevant - Mere change of form/properties inherent to the substance e.g. solubility of the salt/hygroscopicity of a polymorph, without

any enhancement in the efficacy of the known substance, held, would not qualify as ``enhancement of efficacy'' of the known substance for the new form to qualify for independent patent protection - Enhanced efficacy of the new form has to be established with reference to research/empirical data, (2013) 6 SCC 1-G

Intellectual Property

Patents

Ss. 2(1)(j), (ja), 3(d), 6, 7 and 43 - Patent claims - Findings recorded by foreign Patent Authorities - Binding effect of - Appellant claimed to invent ``Imatinib Mesylate'' and ``b-crystalline-Imatinib Mesylate (b-IM)'' from Imatinib-in-free-base-form, a derivative of a chemical compound (N-phenyl-2-pyrimidine-amine) patented under US Zimmermann Patent No. 5,521,184 - United States Board of Patent Appeals while granting US Patent Zimmermann Patent No. 6,894,051 B1 to appellant for b-IM had proceeded on the basis that Zimmermann Patent No. 5,521,184 had the teaching for making of ``Imatinib Mesylate'' from ``Imatinib'' - Appellant, held, is bound by this finding recorded in its own case and cannot make a contrary claim in India that not only b-IM but ``Imatinib Mesylate'' is also a new product (being result of an invention) contending that ``Imatinib Mesylate'' was not there in teaching of Zimmermann Patent No. 5,521,184, (2013) 6 SCC 1-H

Intellectual Property

Patents

Jurisprudential basis - Patent coverage/claim vis--vis enabling disclosures/teachings contained in patent - Limited monopoly to patentee in return for his willingness to place his knowledge in public domain - Patent coverage/claim, held, cannot be wider than disclosures/teachings contained therein - Contrary view negates very basis of patent protection, (2013) 6 SCC 1-I

Intellectual Property

Patents

Ss. 2(1)(m), (j) & (ja), 3 and 83 - Patent Law in India - Development of - Product patents - Scope of - Intrinsic worth of invention - Central consideration of - Held, Patent Law in India should not develop in a manner where scope of patent is determined based not on intrinsic worth of the invention but by artful drafting of its claims by skilful lawyers, and where patents are traded as a commodity not for production and marketing of patented products but to search for someone who may be sued for infringement of the patent, (2013) 6 SCC 1-J

Intellectual Property

Patents

Ss. 2(1)(m), (j) & (ja), 3, 43 and 83 - Patentability/Patent protection in Indian law - Standard of inventiveness, held, is high - Indian Patent Law lays down requirement of ``inventive step'' in S. 2(1)(ja) and ``enhanced efficacy'' in S. 3(d) for incremental improvements of known substances/processes to qualify for patent protection in India - Standard of ``manipulative step'' in United States Patent Law, contrasted - Held, a ``manipulative step'' may or may not be an ``inventive step'', which is the requirement under Indian law - Hence, though appellant was successful in United States in obtaining US Patent for b-crystalline-Imatinib Mesylate since it involved a ``manipulative step'' in respect of existing knowledge, the same did not in present case qualify for patent protection under Indian Patent Law, (2013) 6 SCC 1-K

Intellectual Property

Patents

S. 3(d) (as amended by Amendment Act, 2005) - Scope of - Whether an ex majore cautela (out of abundant caution) clause - Evergreening - Prevention of - Held, S. 3(d) which disqualifies certain inventions/innovations from qualifying for patent protection, is a substantive provision and not an ex majore cautela clause - Amended portion of S. 3(d) sets up a second tier of qualifying standards for patent protection, especially for chemical substances/pharmaceutical products, in order to permit patents for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of patent term on spurious grounds, (2013) 6 SCC 1-L

Intellectual Property

Patents

S. 3(d) & Expln. thereto and Ss. 2(1)(j) & (ja) and 5 (since deleted) and 83 - 2005 Amendments to Patents Act - Amendment of S. 3(d) and deletion of S. 5 - True import in the context of pharmaceuticals and chemicals - Entitlement only of genuinely deserving and real incremental improvements of known substances, to patent protection - Stringent test for granting patent protection to incremental improvements - Purpose of, held, is not to grant patent unless it is a genuinely deserving invention - b-crystalline-Imatinib Mesylate (b-IM) found herein to not be a real nor deserving incremental improvement of known substance under Indian Patents Act and so denied Indian patent - Cautioned however, that failure of b-IM to meet standards of patentability in Indian law is not to be understood as meaning that real and deserving incremental improvements in/of other pharmaceuticals and chemicals would not qualify/meet the said standards - Further held, deletion of S. 5 cannot be interpreted as defeating purpose for which S. 3(d) was amended, (2013) 6 SCC 1-M

Intellectual Property

Patents

Ss. 2(1)(m), (j) & (ja), 3 and 43 - Grant of patent in India - Twin cumulative tests/pre-conditions of - (1) Invention, and (2) Patentability - Held, subject, for grant of patent, must satisfy twin tests of ``invention'' and ``patentability'' - Both are two distinctly separate concepts under Patents Act - Every discovery or innovation is not an ``invention'' for purposes of Patents Act, and every ``invention'' that so qualifies under Ss. 2(1)(j) & (ja) is not patentable if barred under S. 3, (2013) 6 SCC 1-N

Intellectual Property

Patents

S. 2(1)(j) r/w Ss. 2(1)(ac) & 2(1)(ja) and S. 3 - ``Invention'' - Tests/conditions which a product must satisfy to qualify as ``invention'', enumerated - Distinctive, unanticipated and non-obvious innovation coupled with some perceptible industrial or economic advantage - Innovation meeting these requirements and not barred from patent protection under S. 3, held, qualifies as ``invention'' for purpose of patent protection, (2013) 6 SCC 1-O

Intellectual Property

Patents

S. 3 - Inventions - Differential treatment of, for patentability under S. 3 - Held, threshold requirements of patentability for different inventions are different in S. 3, (2013) 6 SCC 1-P

Intellectual Property

Patents

Ss. 5 (since deleted), 3(d), 2(1)(j) & (ja) - Amendments made in 2005 - Significance of - Held, redefined concepts of invention and patentability in India - Further held, the single most important change brought about in Patent Law in India as a result of the country's obligations under TRIPS Agreement was deletion of S. 5 from Patents Act, which re-opened the doors to product patents in India (see also Shortnotes U to Z, below), (2013) 6 SCC 1-Q

Interpretation of Statutes

External Aids

Taken into consideration for determining precise import of amendments brought about in patent law, (2013) 6 SCC 1-R

Intellectual Property

Patents

S. 43 - Consideration of patent claim - Mailbox procedure - Deferring consideration on patent claim, in view of expected changes in patent law - Patent application taken out of mailbox after law was amended - Claim rejected with reference to amended law - In the facts and circumstances, rejection upheld, (2013) 6 SCC 1-S

Constitution of India

Arts. 136, 226 and 227 - Maintainability of SLP - Alternate remedy before High Court - Non-exhaustion of - SLPs directly against order of Intellectual Property Appellate Board (IPAB) - Considering importance of issues involved in the case, SLPs entertained, being: (i) patentability of a life-saving drug, (ii) another Bench of Supreme Court had already heard the matter for some time, (iii) patent might lapse if parties were sent back to High Court, and (iv) there was consensus amongst contesting parties for final resolution of dispute by Supreme Court itself - Cautioned however, that this is not to be taken as a precedent and any attempt to challenge IPAB order directly in Supreme Court side-stepping the High Court, to be strongly discouraged, (2013) 6 SCC 1-T

Intellectual Property

TRIPS Agreement

Significance - Harmonisation of intellectual property laws - Binding effect on WTO members - Held, India being a founding member of GATT and WTO, is bound by TRIPS Agreement, (2013) 6 SCC 1-U

Intellectual Property

TRIPS Agreement

Creation of WTO and TRIPS Agreement, 1995 - Liberalisation of world trade - International protection of intellectual property rights - Impact on Indian patent law - Harmonising approach of India - Held, effort in India has been to meet international commitments under TRIPS Agreement and at the same time to see that common man does not suffer - TRIPS Agreement gave rise to widespread concern in developing and less-developed countries - Protection of intellectual property rights (IPRs) of pharmaceutical/agricultural companies and others at international level was one aspect of matter - Other aspect was to protect basic human rights, namely, proper nutrition, health and health care - India while making significant changes in patent law to meet its TRIPS obligations strove not to lose its reputation as pharmacy of the world - Prices of pharmaceutical and agricultural products could not be allowed to go up beyond certain limits - Amendments brought about in Indian Patent Law in 2004/2005, were outcome of these two competing considerations, (2013) 6 SCC 1-V

Intellectual Property

Patents

Patent regime in India - History traced from 1911 to 2005 - Product patents - Permissibility under 1911 Act, their denial under 1970 Act regime and their restoration vide the 2005 Amendment Act regime, traced, especially the significance of S. 5, Patents Act, 1970, before and after its deletion in 2005 - Reasons therefor, and its implications explored in detail - Patents regime under 1911 Act, held, was more helpful to foreign patentees than to promote indigenous research and industrialisation - Imbalance corrected by 1970 Act, (2013) 6 SCC 1-W

Intellectual Property

Patents

Pharmaceutical/medicine patents - Impact of Patents Act of 1911 on pharmaceutical industry in India and how this industry grew after change in Patent Law i.e. after enactment of new Act of 1970 (prior to 2005 amendment) which denied product patents, delineated, (2013) 6 SCC 1-X

Intellectual Property

Patents

History behind introduction of, traced, including India being taking to WTO Dispute Resolution Panel repeatedly and possibility of imposition of trade sanctions on India for not complying with its obligations under Art. 27 r/w Arts. 70(8) & (9) of TRIPS Agreement to introduce product patents regime, (2013) 6 SCC 1-Y

Intellectual Property

Patents

Change in Patent Law in India - Deletion of S. 5 from Patents Act, 1970 was the most important change which re-opened doors to product patents in India, (2013) 6 SCC 1-Z

Intellectual Property

TRIPS Agreement

Impact on Indian patent law - Hasty amendments to meet deadline, 1-1-2005, fixed for implementing TRIPS obligations - Impact of - Held, loose ends have been left in relevant legislation - This perhaps explains somewhat unclear drafting of some very important provisions, which called for much greater clarity, (2013) 6 SCC 1-ZA

Interpretation of Statutes

Basic Rules

Legislative history - Mischief rule, held, is the best way to understand meaning and purpose of a statute - This is particularly relevant in respect of patent law in India - Legislative history of Patent Law in India (i.e. ``why'' and ``how'' of Patent Law) discussed to understand the present Patent Law, (2013) 6 SCC 1-ZB

Interpretation of Statutes

External Aids

Relied on, (2013) 6 SCC 1-ZC

Interpretation of Statutes

External Aids

Legislative speeches - Relied on, (2013) 6 SCC 1-ZD

Interpretation of Statutes

Internal Aids

Relied on, (2013) 6 SCC 1-ZE

Courts, Tribunals and Judiciary

Judicial Process

Advocates - Contribution to law - Patentability of a pharmaceutical product keenly debated - Younger generation from Bar producing very useful material on aspects which were otherwise very technical - Contribution commended, (2013) 6 SCC 1-ZF