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Pre-Grant Opposition: *CSIR* v *Ms Hindustan Lever Limited*

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The article attempts to provide an overview of the pre-grant opposition against a patent application no 1219/DEL/2004 dated 30-06-2004 filed by the Council of Scientific and Industrial Research (CSIR). The Pre-Grant Opposition was filed by M/s Hindustan Lever Limited by way of Representation u/s 25 (1) of Indian Patents Act, 1970. This resulted in the application being denied to CSIR, by the Assistant Controller of Patents & Design, Indian Patent Office (IPO), New Delhi. Subsequently, CSIR went on to file an appeal against the Order of Assistant Controller of Patents & Design at Intellectual Property Appellate Board (IPAB), Chennai which ultimately resulted in the impingement of the decision of the Assistant Controller of Patents and Designs, IPO, New Delhi by the IPAB on 20-06-2013 and a direction to grant the Patent to CSIR was passed by IPAB, Chennai, and accordingly the Patent was granted to CSIR on 27-08-2015. This study provides an overview of the case, including comprehensive information on the Indian patent filing process, examination procedures, pre-grant opposition, and strategies to address opposition. Furthermore, it presents a comparative analysis of similar cases, highlighting key legal interpretations, and offers suggestions for enhancing institutional IP due diligence processes and strengthening IP safeguards.

Keywords: Patent Application, Intellectual Property Appellate Board (IPAB), Council of Scientific and Industrial Research (CSIR), Hindustan Unilever Limited (HUL), Pre-Grant Opposition

The field of intellectual property rights is governed by respective Acts for the various intellectual properties that one is dealing with, be it patents, trademarks, designs, and copyrights. While dealing with Indian Patents, The Patents Act, 1970[1] and The Patents Rules, 2003 recently amended in 2016 are the overarching Act and rules and details of procedures for Patent filing, prosecution and in related matter patent opposition are governed by the same. There have been an increased rate of infringement and opposition of IPRs, especially those pertaining to technologies which are of high value and the products for the same are having high market value. Some recent cases in intellectual property (IP) opposition and infringement cases have been reported. Kim *et. al.* (2016)[2] did a study to measure the relationships between intellectual property rights (IPR) violations, government effectiveness, and foreign direct investment (FDI) in China. The study confirms that when regulatory enforcement of IPR becomes effective, it is manifested by a rising number of IPR disputes. Torben Schubert (2015)[3], found that partnerships in innovation are bound to increase the risk of infringement of intellectual property (IP) generated through that alliance. Zoey Becker (2022)[4] in a recent article wrote about the patent infringement suit of Modernain covid vaccine related matter and the ruling of judge for the same. Priyadarshini Singh and Gouri Gargate (2021)[5] discussed the legal arena of Intellectual property rights is one such legal area that has evolved with time. IP is very precious in today's economy, and its importance in academic and other R&D institutions. They further discussed its Crucial role in today's economy, and the requirement of understanding the economic intricacies which an IP possessor hold. Ahmar Afaq and Rupal Chhaya (2022)[6], provide insights from cases where intellectual property was offered as security (more specifically as collateral) and analysed its legal implications in the long run. They talk in detail about the legal framework of different jurisdictions and concepts of Licensing and collateral use of IPRs which includes, any infringement of the trademark, or patent, market conditions, etc. This study presents a detailed account of the case, pre-grant opposition, and the tactics utilized to tackle the opposition. Additionally, it incorporates a comparative analysis of analogous

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cases, emphasizing significant legal interpretations, and provides recommendations for improving institutional IP due diligence processes, as well as reinforcing IP safeguards.

The Invention – Details of Technology

CSIR filed a Patent application number 1219/DEL/2004 dated 30-06-2004 entitled **"**Iodizing Agent and Process for preparation thereof" which relates to a novel process for the preparation of the iodizing agent from Pharma grade hydrotalcite and water soluble alkali lodate. The method of preparation of iodizing agent offers the stability of iodine in the formulation of iodized salt. The iodizing agent so prepared is stable and can be effectively used in the formulation of iodized salt, wherein it offers stability to iodine. The invention provides a stable iodizing compound for imparting enhanced stability of iodine in iodized salt. The R&D work of the invention was done at CSIR-Central Salt and Marine Chemicals Research Institute (CSIR-CSMCRI), Bhavnagar. The institute has developed salt iodizing processes in the past which were also patented.[7-9] The institute also developed and patented technologies for improved field- testing kits for UNICEF to monitor iodine stability in iodized salt.[10-12]

CSIR-CSMCRI had also been engaged in discussions with Salt Department, salt manufacturers, and others on iodine stability, and in testing various commercial salt samples, including testing of Annapurna Salt at the request of HUL.[13] The need to develop a highly stable iodized salt was felt by the Institute. There was also a strong desire to prepare stable iodized salt using less pure raw salts for the benefit of marginal salt producers. Another strong motivation was the recognition that to counter the inadequate stability of iodized salt, manufacturers many times put more iodizing agents in the salt and this is of serious concern for several reasons including the fact that India imports the entire requirement of iodine. CSIR-CSMCRI is actively engaged in the development of porous and layered materials including the development of zeolite A and carbonate-exchanged synthetic hydrotalcite (SHT) of edible grade, and have patents in their name for inventions around the processes. The Institute has also licensed some patented technologies.[14-16]

The inventors were aware of the prior art of facile incorporation of all types of anions into the matrix of carbonate-exchanged SHT through a simple calcination process followed by anion uptake. They thus began to explore whether the incorporation of iodate into SHT can impart higher stability. In the course of their studies, they made the invention that the extent of loading of iodate in SHT has a profound effect on iodine stability and that low loading (e.g., 5% w/w) gives excellent stability with virtually no loss of iodine and, accordingly, fixed the loading range to 0.5-10% w/w in the claims drawn up in the patent application. At these low loadings, the additional advantage was a relatively uniform distribution of the iodizing agentin the salt which too is a key requirement.

In 2006, HUL too filed patent applications pertaining to iodate incorporation into layered double hydroxide (LDH) which is another name for SHT. CSIR did not have any knowledge of these patents by HUL at the time of filing their own application, and if known the same would have been cited in the prior art. A subsequent perusal of the patent and repetition of the experiment of the process which should have been for the best mode of practice – clearly showed that CSIR had a much superior invention and an affidavit was filed. It was stated in the affidavit that in the boiling water test conducted, the loss of iodine in solution was as much as 14% whereas in the CSIR case the loss was <2% at 5% loading and <4% at 10% loading. The product had iodine loading of 15% w/w – which is outside the range of claim 5 of the CSIR application. The product also had much lower crystallinity as revealed by powder x-ray diffraction studies. These confirmed that the CSIR product was different and better. Further, compared to iodate uptake of >85% in the case of the CSIR invention, the uptake of iodate of the HUL patent was computed to be only 35%. As estimated by CSIR-CSMCRI, the non-uniformity of distribution of iodine in the iodized salt was also higher for the iodizing agent of (HUL). Thus, CSIR claimed a superior technology / invention with clearly defined claims and supporting examples. Since the preparation of SHT-iodate entails additional expenditure over the conventional art of salt iodization, people would practice the know-how only if the gains are adequate and this is more likely to be the case for the CSIR invention.

CSIR's claimed invention was indeed different from the cited HUL patent (ZA 2000/4598) and the differences are-

a) Compared to the sole example in ZA 2000/4598, wherein the product obtained is amorphous rather than crystalline and iodine loss in solution is as much as 14% in boiling water test, the SHT-iodate

of 1219/DEL/2004 is more crystalline (with well-defined powder XRD peaks) and more stable at the 0.5-10% loading claimed, with <2% iodine loss in boiling water test in the mid-range of 5% loading;

b) Uptake of iodate from solution is high (85-98%) thereby improving the economics of raw material usage and alleviating problems of effluent management; and

c) Salt iodization is more homogeneous.

CSIR invention led to a superior product and a more efficient process compared to the results of HUL's example 1, be it iodine stability or percent uptake of iodate or rate of uptake of iodate, which is sufficient proof of the patentability of the CSIR invention. Since CSIR's patent application was superior to that of HUL's patent, HUL will face tough competition from the market for selling the "Annapurna Iodised Salt" in a condition where CSIR transfers its patent-protected technology to a third party (a competitor of HUL).

CSIR: IP Portfolio Strength

Council of Scientific and Industrial Research (CSIR), India is a prominent R&D organization, under the Ministry of S&T, Government of India and is registered Society under Societies Registration Act, 1860. CSIR strives to be on the forefront in R&D in diverse areas of science and technology providing innovative solution to the needs of the industry - small and big and translating it for well- being of the people of the country. CSIR is a contemporary R&D organization with a network of 37 national laboratories, 39 outreach centres, and 3 Innovation Complexes, with a pan-India presence. Its R&D expertise and experience are embodied in its human capital of about -3521 active scientists supported by about 4162 technical and support personnel. CSIR is the pioneer of India's intellectual property movement with a sizable patent portfolio, of about 2587 foreign patents (in force) and about 1132 Indian patents (in force) in the areas of bio-informatics, leather, optical fiber, drugs and pharmaceuticals, biotechnology, nanotechnology, polymers, food products & processes, herbals and plant varieties. Out of the total of 1,132 unique Indian patents in force, 140 patents, approximately 12.3 % have been commercialized.[17]

Needless to say, CSIR IP Policy is directed to maximise the benefits to CSIR from its intellectual capital by stimulating higher levels of innovation, ensuring timely and effective legal protection for its IP and leveraging and forging strategic alliances for enhancing the value of its IP. This IP policy is implemented and managed by CSIR – IPU, (unit of CSIR HQ), which is devoted to look after the national and international protection of IP generated at constituent CSIR Laboratories.

Effective management of Intellectual Property Rights has placed CSIR as an organization on the global IPR radar. CSIR has received various national and international recognition, a few notable awards among them are National Intellectual Property Awards 2018 and 2022 by Govt. of India; According to SCIMAGO Institutions Rankings 2021, CSIR is in top 25 Government institutions across all regions and countries in Research Rank, and at 119 Position in Innovative Rank among Government institutions across all regions and countries. Clarivate India Research Excellence Citation Awards 2021 in the SDG category; Clarivate South and Southeast Asia Innovation Award 2021; Questel's IP Excellence Award, 2021; Clarivate Analytics India Innovation Awards 2018 in the Government Research Organisation Category etc.

IP Policy of CSIR

The IP Policy of CSIR is "to maximise the benefits to CSIR from its intellectual capital by stimulating higher levels of innovation through a judicious system of rewards, ensuring timely and effective legal protection for its IP and leveraging and forging strategic alliances for enhancing the value of its IP". The aim is to capture, secure and manage the formidable intellectual property asset so as to realize appropriate and commensurate monetary and strategic value from it for CSIR and the nation.

Hindustan Unilever Limited: Company and Outreach

Hindustan Unilever Limited (HUL) is one of India's largest fast-moving consumer goods company with a purpose to make sustainable living commonplace as defined on their website, and has over 85 years of presence in India. The company derives a competitive advantage from new product development, in disruptive technologies through their R&D initiatives with Innovation playing a central role. HUL not only partners with academic institutions, universities, Scientific of national and international stature but also develops products through their strong R&D initiatives. With eight global R&D centres in US, UK, Netherlands, Italy, India and China, they have R&D ecosystems around

the globe. As per their website they have more than 650 science, technology, engineering experts and statisticians in India in cities like Mumbai, Bangalore and Gurgaon, contributing their specialist skills to make best in class products.

Their expertise lies in the following segment - Beauty and Personal Care products, home care products and Foods and nutrition and refreshment products. Beauty products like *Dove, Lifebuoy, Glow & Lovely, Axe, Love Beauty & Planet, Vaseline, Pond's, Lux, Liril, Hamam, Pears, Rexona, Sunsilk, Clear, Closeup, Pepsodent, Lever ayush, Indulekha, TRESemmé, Lakmé and VWash.* Home care products like *Rin, Surf excel, Wheel, Sunlight, Love & Care, Comfort, PureIt, BlueAir, Nature Protect, Vim, Cif* and *Domex*. Foods, Nutrition and Refreshment brand products like *Brooke Bond, Lipton, Kissan, Kwality Wall's, Knorr, Bru, Hellmann's, Annapurna, Horlicks and Boost*.[18]

Patent Filing in India

Indian Patent application may be filed by an individual, an organization, inventor or assignee of inventor/s either alone or jointly with other inventor/ organization in any of the patent offices located in India *viz* Delhi, Kolkata, Chennai, Mumbai. The application is submitted along with filing fees, Form 1 providing proof of right to file the application from the inventor. Form 2 which is provisional / complete specification containing details of disclosure of the invention. Form 3 provides the statement and undertaking under Section 8 along with form 5 providing the declaration to inventorship. The application is published after 18 months after filing the priority application (provisional or complete) in the Official Journal of the Indian Patent Office. The particulars of publication include the following: Application number; Date of filing; Title of the invention; Publication date; International Patent Classification; Name and address of the applicant; Name of the inventor(s); Priority details like priority document number, date, country etc.; Reference to Patent of Addition / Divisional Application along with filing date of the parent Application.; Abstract; No. of claims; Drawings (if any). Subsequent to publication, the Patent Office makes the Specification (complete as well as Provisional, if any), and drawings filed in respect of the application available to the public on its website (Manual of Patent Office Practice and Procedure 2011).[19] The application is examined only after filing a request for examination within 48 months of filing an application along with an examination fee. The fees payable for filing and examination of the application are as per Section 11B and Rules 20(4)(ii) & 24B(1) of The Patents Acts, 1970 and The Patents Rules, 2003 respectively.

Pre-Grant Opposition – Process Thereof

The process of pre-grant opposition is covered under Section 25(1) of The Patents Acts, 1970, and Rule 55 of The Patents Rules, 2003 respectively. According to Section 25(1) of the Act, any individual / representative of any organisation (big or small) can file an opposition to a patent application (patent application is published but not granted) by way of representation to the Controller against the grant of Patent. This application should be filed after the publication of patent application u/s 11A but before the grant of patent, called pre-grant opposition. The timeline for the grant of a patent is such that a Patent is not granted before the expiry of six months from the date of publication under Section 11A. Therefore, a pre-grant opposition may be filed within six months from the date of Publication, to make sure that the pre-grant opposition is filed before the grant of the patent. Such an application is filed with a statement and evidence, in support of such representation and a request for hearing in case so desired. However, the Controller considers the representation only after a Request for Examination for the said Application has been filed by the applicant along with examination fees thereof. In case the Controller is of the opinion that pre-grant opposition has merit and the application shall be refused or amended, a notice is given to the applicant along with a copy of the representation. The applicant can reply to the representation along with a statement of evidence, in support of his application within three months from the date of the notice. The Controller shall consider the statement and evidence filed by the applicant and may either refuse the grant of the patent or ask for the amendment of the complete specification to his satisfaction before the grant of the patent. After considering the representation and submissions made during the hearing, the Controller shall proceed further, either rejecting the representation and granting the patent or accepting the representation and refusing the grant. This process is ordinarily completed within one month from the completion of the above proceedings. If the application for a patent is to be refused on consideration of the pre-grant opposition u/s 25(1), a speaking order of refusal shall be issued under Section 15.

Patent Application Number 1219/DEL/2004 dated 30.06.2004

"Iodizing agent and process for preparation thereof" (grant date 27.08.2015) relates to a novel process for the preparation of the iodizing agent from pharma grade hydrotalcite and water soluble alkali Iodate. The method of preparation of iodizing agent offers stability ofiodine in formulation of iodised salt. The iodizing agent so prepared is stable and can be effectively used in the formulation of iodized salt, wherein it offers stability to iodine.

The Patent Application 1219/DEL/2004 (CSIR) was published on 23-06-2006 u/s 11 (A) of The Patents Act, 1970, subsequently a Pre-Grant Opposition was filed by M/s Hindustan Lever Limited by way of Representation u/s 25 (1) of Indian Patents Act, 1970 on 21-12- 2006. Ensuing the opposition filed by HUL, the case was reported to CSIR by the Indian Patent Office on 01-06-2010. Pertinent to note is that HUL is in the salt business since 1995 under the brand name "Annapurna Salt" and thereafter they have launched "Annapurna Iodised Salt".

Consequently, CSIR filed a response to the said Pre-Grant Opposition at Indian Patent Office, New Delhi. The Assistant Controller of Patents & Design refused the CSIR's patent application u/s 15 of The Patents Act, 1970 on 20-06-2013 after a hearing in the matter which was held on 06-11-2012 at Indian Patent Office, New Delhi. CSIR then filed an appeal against the Order of Assistant Controller of Patents & Design on 18-09-2013 at IPAB, Chennai. The IPAB set aside the impugned decision of the Assistant Controller of Patents and Designs, Patent Office, New Delhi and directed to grant the Patent to CSIR on 27.8.2013.

Grounds of Opposition

HUL raised several grounds for opposition against the patent application (No. 1219/DEL/2004) under The Patents Act, 1970. The opposition was based on the following grounds:

(i) Anticipation by Prior Publication (Section 25(1)(b)): HUL argued that the invention claimed in the application had been published before the priority date of the claim either in specifications filed in India or in any other document. HUL presents several documents, including patents and publications, which they believe anticipate the claims made in the application.

(ii) Prior Claiming (Section 25(1)(c)): HUL asserted that a claim similar to the invention had already been made in a patent (Indian Patent No. 193455) with an earlier priority date. Therefore, they argue that the application is liable to be rejected on the ground of prior claims.

(iii) Prior Public Knowledge and Use (Section 25(1)(d)): HUL claimed that the invention, as claimed in the application, was publicly known or used in India before the priority date of the claim. They contended that the various prior arts and publications referred to in their argument demonstrate that the invention was already known to the public.

(iv) Obviousness and Lack of Inventive Step (Section 25(1)(e)): HUL alleges that the invention lacks the inventive step based on the prior publications and patents cited. They argued that the optimization and parameters used in the application are routine and obvious to a person skilled in the art, and therefore, not worthy of patent protection.

(v) Not an Invention or Patentable Invention (Section 25(1)(f)): HUL claims that the subject matter of the invention does not meet the criteria of being an invention under the Patents Act and is not patentable.

(vi) Lack of Clarity and Insufficiency of Description (Section 25(1)(g)): HUL asserts that the complete specification of the invention does not sufficiently and clearly describe the invention or the method by which it is to be performed.

(vii) Failure to Disclose Details of Corresponding Foreign Applications (Section 25(1)(h)): HUL argues that the applicant has failed to disclose the necessary information required by Section 8 of the Act regarding corresponding foreign applications.

HUL provided detailed comparisons between the claims in the impugned application and the prior publications, highlighting similarities and arguing that the claimed invention lacks novelty, inventive steps, and unexpected benefits. They also pointed out discrepancies in temperature details and the lack of superiority demonstrated by the application's claims. HUL has filed an evidence affidavit supporting their arguments and stating that the properties of the ingredients used in the application are not significantly different from existing standards. They further questioned the impact of certain process variations and claim that the application fails to provide data supporting the benefits of specific steps.

Clarification Provided by CSIR

CSIR submitted a reply statement to the representation of opposition, addressing various points raised by the opponent. CSIR highlighted the following points:

Firstly, regarding the allegation that the South African Patent No. ZA 2000/4598 teaches the essential features of the applicant's invention, CSIR stated that they did not come across this patent during their prior art search and only became aware of it through Hindustan Unilever Limited (HUL) and a formal letter from the HUL. They argued that the methodology of anion uptake described in the HUL's patent is not significantly different from the prior art described in Parker et al., which they relied on for their own invention.

CSIR further argued against the HUL's objection over grinding of pharma grade HT, stating that grinding is necessary for uniform calcination, while the use of pharma grade HT ensures control over impurities. They also counter the allegation that the iodine content in the CSIR's invention falls within the range of ZA 2000/4598, pointing out that the loading of iodine in their product is significantly lower and results in greater crystallinity compared to the prior art.

CSIR emphasizes that the focus should be on the finer understanding of the process that imparts maximum stability to iodate, which is the key reason for incorporating iodate into their invention. They argue that the loading of iodate in their invention is different from ZA 2000/4598 and has a profound effect on the stability and crystallinity of the product.

Regarding the use of elevated temperature to expel dissolved carbon dioxide, CSIR explains that SHT incorporates iodate due to the loss of CO_2 on calcination, which is reversible. They stated that the use of high temperature is a common step in the prior art and helps reduce the loss of potency of the calcined SHT.

CSIR also addressed the HUL's objections related to calcining temperature, concentration of metal salt, the use of pharma grade HT, and prior claiming. They argued that their specified parameters are necessary for achieving the desired iodine loading, stability, and uniform distribution of iodine in the salt.

In response to the HUL's assertion that the applicant's process is based on ZA 2000/4598 and lacks inventive step, the applicant stated that they relied on the teaching of Parker et al. and their own invention, and the cited document does not make their application obvious or lacking in inventive step.

CSIR rebuts HUL's claims regarding Indian Patent No. 193455, stating that there is no disclosure in the claims that covers what is disclosed in their application. They also argued that the HUL's patents are irrelevant, as they were not cited in any patent application of CSIR.

Regarding HUL's claim of using the process of ZA 2000/4598 for making their product, CSIR questioned the evidence provided and emphasizes the superior nature of their own invention in terms of product specifications, stability, and uniformity of distribution.

Finally, CSIR asserted that they have provided the necessary information and undertaking under Section 8, and the ground of opposition stands carried away due to the allowance of a petition.

In conclusion, CSIR argued that their invention differs significantly from the prior art and that their process and product specifications demonstrate inventiveness and superior performance compared to HUL's claims. They refuted the allegations of lack of novelty, obviousness, and prior claiming.

Findings and Judgement

The summary of the findings in the case of the impugned Patent Application No.1219/ DEL/2004 is as follows:

The opposition was filed by HUL against the originally filed set of 11 claims of the CSIR. CSIR later amended the claims, resulting in a finalized set of 07 claims.

Final 07 claims:

1. *A method for the preparation of iodizing agent that offers stability of iodine in formulation of iodised salt, the method comprising:*

(i) grinding pharma grade hydrotalcite to obtain hydrotalcite powder passing through 60 BSS mesh; (ii) calcining the hydrotalcite powder to obtain calcined hydrotalcite; (iii) cooling the calcined hydrotalcite at 60-80°C to obtain solid synthetic hydrotalcite with an interlayer space within said solid synthetic hydrotalcite ;(iv) heating an aqueous alkali metal iodate salt-solution at temperature ranging between 60-80°C; (v) adding calcined hydrotalcite obtained in step (iii) into the preheated water soluble alkali metal iodate salt solution prepared in step (iv) under stirring at 60-80°C and maintaining this temperature range throughout to obtain uniform dispersion of iodate in the hydrotalcite; (vi) aging the slurry for a period between 30 to 60 minutes with intermittent stirring for 1 minute at an interval of 30 minutes for effective contact and substitution of anions in the interlayer space; (vii) filtering the slurry to remove the water soluble alkali metal iodate salt

solution to obtain a solid synthetic hydrotalcite cake and washing the solid synthetic hydrotalcite cake so obtained with distilled water to remove adhering salts therefrom; (viii) drying the solid synthetic hydrotalcite cake to get the iodizing agent.

2. A method as claimed in claim 1, wherein water soluble alkali metal iodate salt is potassium iodate.

3. A method as claimed in claim 1 wherein the hydrotalcites powder is calcined at a temperature in the range of 450°C to 550 °C for 30 to 75 minutes followed by cooling to 60-80°C.

4. A method as claimed in claim 1 wherein the concentration of water soluble alkali metal iodate salt metal salt in the water soluble alkali metal iodate salt solution is in the range of 0.005 to 0.022 molar.

5. A method as claimed in claim 1 wherein the iodine content in the iodizing agent is in the range of 0.5-10.0% (w/w).

6. A method as claimed in claim 1 wherein the iodate-containing synthetic hydrotalcite was dried in an oven at 80-110°C to expel all moisture to obtain the iodizing agent.

7. A method for the preparation of iodizing agent that offers stability of iodine in formulation of iodised salt substantially as herein describe with reference to examples accompanying this specification.

Grounds I & II: CSIR's use of pharma grade HT (High Test) does not provide any inventive element to the process, as there is no material difference between pharma grade HT and commercially available HT. The claim related to this has been removed from the finalized set of claims. CSIR relied on the teaching of Parker et al. and its own invention for incorporating iodate into calcined SHT (Salt Hydrate Technology) to achieve stability and uniform distribution, which would not have been obvious from the teaching of Parker et al.

Ground III: There is no evidence to support the allegation that the alleged invention was publicly known or used in India before the priority date. This ground is not sustained.

Ground IV: The use of pharma grade HT and the method of iodate incorporation draw on prior art, but CSIR claims that the maximum uptake of iodate can be obtained through control of concentration and solution temperature, which was not considered in the prior art. The range of parameters used in the impugned application overlaps with those of a cited document (South African Patent No. ZA 2000/4598). The optimizations carried out by the CSIR are routine and obvious to a person skilled in the art, and thus, lack an inventive step.

Ground V: Due to the lack of an inventive step, the claimed invention is not considered patentable.

Ground VI: The terms used in the specification are well-known in the art, and insufficient description is not sustained.

Ground VII: CSIR has provided information and an undertaking regarding corresponding foreign applications, so this ground of opposition is not sustainable.

The Assistant Controller of Patents & Design refused the Council of Scientific and Industrial Research (CSIR) patent application 1219/DEL/2004 dated 30.06.2004 u/s 15 of Indian Patents Act, 1970 on 20.06.2013 as a consequence to the pre-grant opposition was filed by M/s Hindustan Lever Limited (HUL), after a hearing in the matter which was held on 06.11.2012 at Indian Patent Office, New Delhi.

The Appeal in the IPAB and Final Judgement

CSIR filed an appeal against the Order of Assistant Controller of Patents & Design on 18.09.2013 at IPAB, Chennai. The appeal in question revolves around the issue of whether the CSIR's claimed invention is patentable. To determine this, it is necessary to refer to the definition of the invention as provided in Section 2 of the Patents Act, 1970, as interpreted by the Supreme Court in the case of *Novartis AG & Others* v *Union of India & Others* (2013) 54 PTC 1 (SC). The definition requires a product to fulfill three conditions to qualify as an invention: it must be new, involve an inventive step, and be capable of industrial application. The concept of inventive step is separately defined in Section 2(ja) as a feature of an invention that represents a technical advance compared to existing knowledge or has economic significance, or both, making the invention not obvious to a person skilled in the art. In order to qualify as an "invention," a product must satisfy the tests of novelty, industrial applicability, and the presence of an inventive step. IPAB observed that the Patents Act distinguishes between "invention" and "patentability" as separate concepts. Granting a patent requires satisfying both the criteria of invention and patentability.

The Assistant Controller rejected CSIR’s patent application primarily on the grounds of lack of inventive steps / non-obviousness. However, CSIR’s reply statement addressed each ground of opposition and provided crucial differences between their claimed invention and the cited prior art, supported by actual experimental results. CSIR demonstrated improved

effectiveness and filed uncontroverted declarations of the inventors, which the Assistant Controller failed to consider. The Assistant Controller relied on a prior-art document, ZA2000/4598, and emphasized its relevance without adequately considering the differences demonstrated by the CSIR. CSIR highlighted specific process steps that showed high iodate uptake, uniform distribution of iodine, stability, and reduced time consumption compared to the prior art. CSIR argued that these steps constituted a novel and inventive process and were not mere optimization. The Assistant Controller's reliance on another prior-art document, Kameda-et al., was contested by the CSIR, asserting that it was from a different field of technology unrelated to iodine absorption. The Assistant Controller's finding that CSIR's process steps were within the range of the cited documents was deemed erroneous.

IPAB examined the materials on record, experimental results, and the highlighted differences, concluding that CSIR's claimed invention met the criteria of novelty and inventive steps / non-obviousness. CSIR satisfied the requirements of invention and patentability. Consequently, the IPAB set aside the impugned decision of the Assistant Controller of Patents and Designs, Patent Office, New Delhi dated 20.06.2013 and directed to grant the Patent to CSIR after an appeal against the Order of Assistant Controller of Patents & Design on 18-09-2013 at IPAB, Chennai. Accordingly, the Patent was granted to CSIR on 27.08.2015.

Comparisons with Precedents on Interpretation of Law

1. *CSIR* v MS *Hindustan Lever Limited* involves a pre-grant opposition filed under Section 25(1) of the Indian Patents Act, 1970. A relevant precedent for comparison could be the case of *Bishwanath Prasad Radhey Shyam* v *Hindustan Metal Industries* (AIR 1982 SC 1444).[20] In the Bishwanath Prasad case, the Supreme Court of India made a significant ruling regarding the authority of the Controller of Patents in granting patents, refusing them, or amending the complete specification based on a pre-grant opposition filed. In the Bishwanath Prasad case, the Supreme Court established the scope of power vested in the Controller of Patents. The court held that the Controller of Patents has the authority to make decisions on the grant, refusal, or amendment of a patent's complete specification, taking into account the pre-grant opposition filed by interested parties.

This precedent is relevant to the *CSIR* v *HUL* case because it establishes a legal framework for the decision-making process of the Controller of Patents. The Supreme Court's ruling in Bishwanath Prasad case sets a precedent for how the Controller of Patents should exercise their authority in similar cases, including the one involving CSIR and HUL.

In the *CSIR* v *HUL* case, the pre-grant opposition filed under Section 25(1) of the Indian Patents Act allows interested parties, such as CSIR, to present their objections or concerns regarding the patent application before it is granted. This pre-grant opposition mechanism serves as a crucial opportunity for third parties to raise valid points or evidence that could potentially impact the decision on whether to grant the patent or make amendments to the patent's complete specification.

Considering the Bishwanath Prasad case, where the Supreme Court affirmed the Controller of Patents' authority to consider pre-grant oppositions, it is likely that the court in the *CSIR* v *HUL* case would take a similar stance. The Controller of Patents in this case would be expected to thoroughly assess the pre-grant opposition filed by HUL and make an informed decision on the grant, refusal, or amendment of the patent application based on the merits of the opposition. Overall, the Bishwanath Prasad case serves as a relevant precedent for the *CSIR* v *HUL* case, as it establishes the authority of the Controller of Patents to decide on the grant, refusal, or amendment of a patent's complete specification, considering the pre-grant opposition filed under Section 25(1) of the Indian Patents Act, 1970.

2. The case of *Novartis AG* v *Union of India* (AIR 2013 SC 1311)[21] is an important precedent that provides guidance on the interpretation of Section 3(d) of the Indian Patents Act. Section 3(d) specifically addresses the patentability of new forms of known substances and sets certain criteria that must be met for such inventions to be eligible for patent protection.

In this case, Novartis AG, a multinational pharmaceutical company, was seeking a patent for a new form of a known substance called imatinib mesylate, which is used in the treatment of chronic myeloid leukemia. The patent application was challenged by the Union of India on the grounds that the new form did not meet the requirements of Section 3(d). The Supreme Court of India, in its judgment, provided a significant interpretation of Section 3(d). The Court ruled that for a new form of a known substance to be granted a patent, it must demonstrate significantly enhanced efficacy compared to the known

substance. The court emphasized that the mere discovery of a new form of a known substance, without demonstrating enhanced therapeutic efficacy, would not qualify for patent protection. This interpretation of Section 3(d) by the Supreme Court has far-reaching implications for patent applications related to new forms of known substances in the pharmaceutical industry. It sets a high standard for patentability, ensuring that patent protection is granted only to innovations that offer substantial improvements in efficacy, thereby preventing the granting of patents for trivial modifications or variants of existing drugs. The Novartis case establishes an important precedent for the determination of patentability under Section 3(d) of the Indian Patents Act. It provides clarity on the requirement of significantly enhanced efficacy for the patentability of new forms of known substances. This interpretation has since been influential in subsequent cases involving similar patentability issues in the pharmaceutical sector.

As a result of the Novartis judgment, patent applicants seeking protection for new forms of known substances must demonstrate the enhanced efficacy of their invention through substantial evidence. This ruling promotes innovation by incentivizing the development of truly ground breaking and effective new forms of known substances, while preventing the granting of patents for minor modifications or trivial variations that do not offer significant therapeutic benefits. Novartis case serves as an important precedent in interpreting Section 3(d) of the Indian Patents Act. It establishes the requirement of significantly enhanced efficacy for the patentability of new forms of known substances and has had a profound impact on patent applications and the pharmaceutical industry in India.

3. In the case of *Novartis* v *Cipla* in 2011 (593/CHENP/2005),[22] Novartis filed a patent application in 2005 for "Dispersible tablets comprising Defracirox." However, Cipla filed a pre-grant opposition against this application based on sections 25(1)(e), 25(1)(f), and 25(1)(h) of the Patents Act. The Controller, Dr. Subramaniyan from the Chennai Office, rendered decisions on the issues of novelty, inventive step, and non-inventiveness (Section 3), considering the arguments put forth by both the opponent and the applicant.

Regarding the inventive step, the Controller noted that there was a lack of detailed information on the preparation method for the dispersible tablet with four phases. The applicant's description did not provide specific teachings regarding process parameters for preparing certain phases or any specific improvements in the conventional steps involved. The Controller concluded that the steps used in the invention were routine in the pharmaceutical formulation industry without any specific enhancements. Additionally, the dosage range fell within the prior art, and altering the dose and dosage regimen within that range could not be considered inventive. Independent claim 1 was also deemed lacking in inventive step since the dispersible tablet was already disclosed as one of the choices of medicament in the prior art.

Furthermore, the Controller found that the applicant failed to disclose the active pharmaceutical ingredient (API) and excipients in specific proportions in any composition or new drug delivery system for a known drug. Additionally, support regarding the unforeseen effect of the composition or new drug delivery system with the closest prior art was lacking in the specification. As a result, claims 1, 2, 13, and their dependent claims were deemed to lack inventive step under Section 25(1)(e) of the Act.

In terms of non-invention under section 3, the Controller outlined three specific requirements that the applicant needed to fulfill. Firstly, all the components of the invention had to be incorporated into the principal claim to ensure novelty and inventive step. Secondly, the necessary ingredients, including the API and excipients, had to be included with their respective proportions in the principal claim. Lastly, support relating to an unexpected synergistic effect had to be incorporated into the specification. The Controller concluded that even though the subject matters of the claims had been combined to form a composition claim, the resulting composition was still considered an admixture because each ingredient in the composition functioned as intended, resulting in an additive effect. Therefore, the claims were not patentable under Section 25(1)(f) of the Act.

4. In the case between *Hindustan Lever Ltd*. v *Godrej Soaps Ltd*. [11 April, 1996, AIR 1996 Cal 367][23], Hindustan Lever filed a patent application in India on 14.10.1992. The patent application claimed two priorities from the United Kingdom, dated 14.10.1991, and 14.07.1992. The patent was granted on 18.05.1996.

Godrej Soaps opposed the patent application, citing several grounds for opposition. These included anticipation by prior publication, prior public knowledge and usage, lack of inventive step and

obviousness, non-patentability under the Patent Act of 1970, inadequacy and clarity issues in the description, and failure of the applicant to disclose required information to the Controller of Patents or providing false information related to a particular material as per Section 8 of the Patent Act of 1970. During the hearing, the court found that the evidence provided by Godrej Soaps was inadequate to prove the grounds mentioned in the opposition application. Subsequently, the applicant (Hindustan Lever) amended the specifications and claims to clarify their points and overcome the allegations made by the opponents.

After carefully considering the notice of opposition, statements, and supporting evidence from both parties and conducting the necessary hearings, the court dismissed the opposition to the patent. The court concluded that the amended specifications and claims addressed the concerns raised by the opponents. Therefore, the patent application filed by Hindustan Lever was allowed to proceed without any further opposition.

Analysis and Core Aspects of the Case

Grounds of Opposition

HUL raised several grounds for opposition against the patent application (No. 1219/DEL/2004) filed by the CSIR under the Patents Act, 1970. The grounds of opposition include anticipation by prior publication, prior claiming, prior public knowledge and use, obviousness/lack of inventive step, not an invention or patentable invention, lack of clarity and insufficiency of description, and failure to disclose details of corresponding foreign applications.

HUL's Arguments

HUL presented various documents, including patents and publications, to support their arguments against the claimed invention. They highlighted similarities between the impugned application and the prior publications, questioning the novelty, inventive step, and unexpected benefits claimed by CSIR. HUL also raised concerns about discrepancies in temperature details and the lack of superiority demonstrated by CSIR's claims. They further criticized certain process variations and the lack of supporting data.

CSIR's Reply

CSIR provided a reply statement addressing the points raised by HUL. They argued against the allegations of anticipation and prior claiming, stating that their invention differs significantly from the prior art and relies on the teaching of Parker et al. CSIR defended their use of pharma grade HT and the incorporation of iodate, emphasizing the differences and the superior performance of their invention. They also addressed objections related to calcining temperature, concentration of metal salt, and the use of pharma grade HT. CSIR refuted HUL's claims of lack of inventive steps and argued that their process and product specifications demonstrate inventiveness and superior performance.

Findings and Judgment

The Assistant Controller of Patents & Design initially refused CSIR's patent application based on opposition filed by HUL on various grounds, including lack of inventive steps. However, the IPAB reevaluated the case and observed that CSIR's claimed invention met the criteria of novelty, and inventive steps. The IPAB concluded that CSIR's claimed invention satisfied the requirements of both invention and patentability, overturning the Assistant Controller's decision. As a result, the patent was granted to CSIR.

Key aspects of the case included the examination of the claimed invention's novelty, inventive steps, and as well as the analysis of prior publications and their relevance to the impugned application. The arguments put forth by both HUL and CSIR were crucial in establishing the distinctiveness and inventive steps of the claimed invention. The case highlights the importance of providing supporting evidence, experimental results, and addressing each ground of opposition in a comprehensive manner. Eventually, the IPAB's judgment determined the patentability of CSIR's invention and granted the patent based on their findings.

Conclusion

Through an examination of patent opposition cases, institutions can establish robust safeguards to protect their intellectual property (IP). These safeguards serve as preventive measures against challenges to the validity and enforceability of their patents. Analyzing such cases allows organizations to identify common patterns and strategies opponents employ to challenge patents. Armed with this knowledge, institutions can proactively address potential weaknesses and strengthen their IP protection strategies. One way, institutions can build safeguards is by implementing rigorous patent drafting and review processes, which

may involve engaging experienced patent attorneys or IP professionals who specialize in the relevant technology domains. Through meticulous drafting and thorough review, organizations can ensure that their patents are accurate, comprehensive, and capable of withstanding potential challenges. Furthermore, institutions can establish internal procedures to monitor and assess the patent landscape in their respective fields. By staying informed about new patent filings, granted patents, and emerging technologies, organizations can proactively identify any potential infringements or threats to their IP. This allows them to take timely action, such as initiating defensive measures or engaging in licensing discussions, to protect their IP rights. Additionally, institutions can consider establishing collaborations and partnerships with other entities, such as universities, research institutions, or industry players. Collaborative efforts enable the sharing of knowledge, resources, and expertise, while also providing an opportunity to collectively address IP challenges. By pooling their intellectual assets and working together, organizations can create a stronger defense against potential infringements and foster innovation within their respective industries. Overall, the analysis of patent opposition cases offers valuable insights and learnings that can be leveraged to enhance due diligence practices and establish safeguards for intellectual property. By incorporating these findings into their IP processes, institutions can strengthen the quality and protection of their inventions, ultimately encouraging a more robust and innovative ecosystem.

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