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A REVIEW OF RECENT PATENT OPPOSITION CASES

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Rachna Bakhru and Suvarna Pandey of RNA consider the recent trends in life sciences patent opposition, and offer advice on how to achieve sufficient disclosure in patent applications along with addressing the patentability issues for diagnostic kits

Opponents in patents opposition cases in the life sciences are now actively relying on grounds of non-patentable invention, under section 3 of the Patents Act (Act) 1970 (which provides a list of inventions belonging to certain domains which are excluded from patentability). Opponents also

tend to attack inventions based on traditional patentability criteria of lacking novelty and inventive step. Lack of sufficient disclosure appears to be the most favoured ground of opposition, having been raised in the majority of cases.

Diagnostic process

Recently, the Indian Patent Office (IPO) decided to grant a patent in the diagnostic domain. This is noteworthy, since in the past most applications based on diagnostic processes or diagnostic kits have been rejected by the IPO based on section 3(i) of the Act, which excludes diagnostic process from patentable subject matter. However, there is no remark about whether the excluded diagnostic process has to be in-vitro or in-vivo.

Application 693/Kol/2007, filed by Lalit Mahajan, relates to a 'device for detection of antibodies to HIV and p24 antigen of HIV1 in human serum or plasma'. In this case, the opponent, QualPro Diagnostic, relied on multiple grounds including: the invention not being patentable under section 3(i) as a diagnostic kit, lack of inventive step; and, insufficiency of disclosure.

The core issue in this case was whether a device for the detection of antibodies in human serum or plasma was excluded from patentability under section 3(i), as it was a method of treatment. However, the controller allowed the claim for diagnostic kit on the basis that the application had claims on the physical constructional features of the device.

While, in terms of inventive step, the controller opined that the device resulted in improved efficacy in the determination of HIV antibodies.

Generally, it is seen that for diagnostic kit claims, the examiner raises objections based on the reasoning that components of the kit constitute prior art. However, the controller in this case clarified that when components of a device are not new but are combined to produce better results in a more expeditious and economical manner, it is patentable. Therefore, inventive step was acknowledged for the present invention.

The controller, while determining the insufficiency of disclosure, mentioned that the description must describe 'an embodiment' of the claimed invention and must be sufficient to enable those in the industry to carry it out, which has been provided by the present invention. The controller proceeded to allow the application for grant.

Another related application of 696/Kol/2007 was filed by the same applicant and opposed by Qualpro Diagnostic, which had claims only on the 'device for rapid, simultaneous and differential detection of p24 antigen & antibodies to HIV-1 and HIV-2'. The device is made of polystyrene material in the form of a comb with eight teeth coated with four dots HIV-1, HIV-2, p24 and a control dot. The devices claimed in

'693 and '696 differ in respect of the coating of dots with appropriate antigens and antibody (which actually changes the immunological reaction) for detection of p24 antigen. This application was mainly opposed on the grounds of insufficiency of disclosure, the technical problem not being defined, objectives not being met, and lack of novelty and inventive step. The controller found the following important issues while deciding the case to be allowed for the grant of patent: (i) for sufficiency of disclosure prior art in the specification is not mandatory for disclosing the invention; (ii) reformulation of the objective problem and inventive step is not allowed during the hearing; and, (iii) novelty and inventive step of the diagnostic kit could be acknowledged in terms of achieving higher sensitivity and specificity.

Therefore, for a diagnostic device, claims in the form of physical constructional features are often allowed as a matter of practice by the IPO. For diagnostic kits made from a combination of known components, it is recommended to show that the combination either provides a new result or an old result in a more economical or efficient manner. The enhanced sensitivity and specificity of the diagnostic kit needs to be shown shown for establishing inventive step; for example, in the '693 application, the controller acknowledged that control dots reduced number of steps and time to perform the test.

Inventive step: simplicity no bar to invention

The following cases illustrate that despite having simpler inventive step, the ability to provide technical advancement over prior art is sufficient to comply with the inventive step requirement.

In application 3871/Delnp/2005, filed by Lonza Biologics, relating to antibody purification by Protein A and Ion Exchange chromatography, the opponent (Glenmark Pharmaceuticals) filed opposition on the grounds of Lack of novelty and inventive step, invention known in prior art and specification not sufficiently described.

"The ability to provide technical advancement over prior art is sufficient to comply with the inventive step requirement"

The controller, while allowing the application, stated that the specific sequence of steps and specific conditions used for the purification of antibodies resulting into higher step yield and the cumulative yield of the process, amounts to inventive step. The controller in this case, specifically stated that 'standardisation of chromatographic techniques in specific sequence and counterbalancing the effects to obtain antibodies of desired purity and yield require inventive step'.

In the application 6618/Delnp/2006, which was filed by Abbot Biotechnology, the controller acknowledged a simple process as novel and inventive based on the so-called teaching away of prior arts from the invention. The invention was related to a multi-variable dose regimen for treating TNF alfa related disorders and claimed a pharmaceutical composition comprising human TNF alfa antibody or antigen binding fragment (Fab fragment) in a particular amount range with a carrier. The opponent (Glenmark Pharmaceuticals) opposed the application on the grounds of novelty, inventive step, the invention being mere admixture (section 3(e)) and the invention being a method of treatment (3(i)).

The controller, while deciding the case, mentioned that 'since all components of the composition were not present in a single cited document, the invention was considered as novel'. Further, based on the efficacy data submitted by the applicant, the grounds of inventive step and invention being 'mere admixture' were dropped. The claims allowed were those: which disclosed the amount and range of the active ingredient; where the treatment and the induction amounts were specified (40 to 60% of the induction amount); and, where the amount and range of active ingredients and excipients was claimed.. The important factor in this decision here was that the controller recognised the efficacy of the range of the components of the composition and the teaching-away technical feature while determining the inventive step.

Inventions relating to biological resources

Of late, inventions relating to biological sources have been questioned during prosecution or opposition over factors including novelty and inventive step with respect to the Traditional Knowledge Digital Library (TKDL) citation and for insufficiency of description.

Application 3387/Delnp/2004, filed by Indena, relates to the formulation useful in the treatment of male and female impotence. The application was opposed by the Council for Scientific and Industrial Research (CSIR) on grounds of: lack of novelty and inventive step; invention as traditional knowledge; mere admixture; and invention lacking efficacy causing it to fall under section 3(d). The controller rejected the application, considering the selection of a known material for incorporation into a composition based on its suitability for its intended use, as a prima facie obvious matter. Where the claim was on the specific combination of extracts in a particular weight, the controller considered novelty; however, while judging the inventive step stated that in the absence of demonstration of unexpected results from the claimed parameters, the optimisation of working conditions such as percentage, temperature, and pressure is considered obvious.

Application 1556/Kol/2007, filed by the Department Centre for Biotechnology, relates to 'pharmaceutical composition and process thereof (stirring process) for the preparation of plant extracts for treating

skin disorders and enhancing healing of wounds'. The application was opposed by the CSIR on the grounds of lack of novelty and inventive step. However, the main objection was over an extract which was an optional component of the composition and its use for any skin disorder. The opponent made no reference to the extract which was the essential component. Therefore, the controller acknowledged novelty of invention in the absence of any documentary evidence about the extract of *Plectranthus amboinicus* (the essential component) prepared by the stirring method and its use for wound healing, and inventive step in terms of determining that the stirring separation technique, which is fast and yields more juice, as the technically advanced feature as compared to the processes of existing knowledge.

The application of 212/Del/2006, filed by S Trivedi, relates to the herbal preparation for the prevention and management of various types of carcinoma. It was opposed by the CSIR on the grounds of: lacking inventive step under section 3(e) (invention as an admixture of the components) and section 3(p) (invention as the aggregation of traditional knowledge); and the National Biodiversity Authority requirement to detail the source and geographical origin of the plant. The controller acknowledged the novelty as the specific amount and the process parameter were not disclosed in the prior art. However, inventive step was found lacking as the applicant failed to furnish negative experimental data. Further, due to the absence of any comparative data or unexpected surprising result, the invention was considered to be a mere admixture. Also, the decision mentioned that nothing inventive could be seen in the use of herbs for the treatment of cancer, as such herbs were already known for the same purpose. Therefore, the invention fell under traditional knowledge and the application was rejected. From this decision, it is evident that an invention relating to traditional knowledge must provide comparative analysis with respect to prior art and simultaneous negative experimental data to substantiate the technical significance of the selected parameters and components.

Application 526/Delnp/2005, granted to Abbott Biotechnology, relates to the 'formulation of human antibodies for treating TNF Alpha associated disorder'. It was opposed by Glenmark Pharmaceuticals on various grounds including: invention as prior claimed; lack of novelty and inventive step, mere admixture and insufficient description. The applicant had claims on the pharmaceutical formulation comprising antibody in the buffer solution comprising citrate and phosphate. The applicant later on amended claims to focus on the use of a higher concentration of antibody and the combination of phosphate and citrate buffer as the inventive component to overcome the teaching of prior art. However, there was no disclosure about the combination of buffers being essential for achieving the desired effect in the description of the specification.

The controller, in discussing the sufficiency requirement, stated that the

invention must describe an embodiment of the invention claimed in each of the claims, and must be sufficient to enable the industry concerned to carry it into effect without undertaking further experiments.

Sometimes, the applicant goes beyond the original boundary of the claims while overcoming the objections cited in view of prior art, which happened in the present case. In such case, the applicant may be successful in their plea for novelty and inventive step; however, the claims may not be sufficiently supported by the description. It is therefore important to properly highlight and provide illustrations for the novel and inventive step of the invention while filing the specification at its first instance.

Takeaway points

Based on the discussed decisions and the practicing manual, we suggest a range of measures to ensure a specification has sufficient disclosure.

The applicant should provide at least one method for performing the invention covering the whole subject-matter claimed in the claims.

Claims to antibodies with therapeutic potential should be supported by defining their role for the target protein in a specific disease and should be substantiated by sufficient data.

An invention should disclose the source and geographical origin of the biological resource (if used), and inventions using biological resources (unavailable to the public), should deposit the biological material and its reference should be made in the specifications. Permission should be sought form the National Biodiversity Authority if the biological resource is obtained from India.

The sequence listing of nucleotides and amino acids (if used) should be filed in electronic form.

For specifications disclosing a wide range of unrelated diseases as the potential therapeutic target of a claimed gene or encoding protein, evidence should be provided to prove a therapeutic or diagnostic use.

If DNA sequences are claimed on the basis that they hybridise with a specifically identified probe and that they possess a certain activity, the claim should be supported with hybridisation conditions.

The above decisions may not be considered as landmark and no guarantee may be given that the Patent Office will opine on similar lines for similar cases in the future. Decisions may vary from case to case and even from controller to controller. However, these cases can be used as a reference and cited as precedents.

RACHNA BAKHRU

Rachna Bakhru is a partner with RNA. She heads the dispute resolution team of the firm, and is heavily involved in IP enforcement including civil and criminal litigation. She qualified as a science graduate from Delhi University, followed by diploma in business administration and a Bachelors degree in law from Delhi University.

Rachna has over 15 years' extensive experience in managing non-contentious and contentious IP matters in India, ranging from brand clearances and risk assessment to litigation and alternate dispute resolution. She has worked on the portfolios of large international companies and her industry expertise includes pharmaceuticals and information technology. She advises her clients on issues related to data protection, software piracy, domain disputes and online infringement.

Prior to joining RNA, Rachna worked for 10 years at the leading international IP consultancy firm Rouse, heading the dispute resolution team for India. She has authored a number of articles for leading IP publications analysing challenges in enforcing and protecting pharmaceutical trade marks, issues surrounding grant of patents for pharmaceutical preparations and changing landscape of the IPR environment.

Rachna is a member of the Bar Council of India and a registered patent agent. She was highly recommended and ranked as the world's leading pharmaceutical and life sciences patent litigator in 2010 by *Intellectual Property Asset Management IAM*.

SUVARNA PANDEY

Suvarna Pandey is an associate with RNA IP Attorneys. She is a registered patent agent and a law graduate. Having been in the practice for over seven years, her specialties include patent searches, patent drafting, patentability and infringement opinion and other technical aspects associated with patenting. She is also involved in patent prosecution proceedings at the patent office, opposition and other invalidity proceedings. She specialises in the development and

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