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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% *Date of Decision: 15th May, 2026*

\+ C.A.(COMM.IPD-PAT) 26/2024

RAYNER SURGICAL IRELAND LIMITED PREVIOUSLY OMEROS CORPORATION .....Appellant

Through: Ms. Ardra Goodwin and Mr. Pallaash Shankhdhar, Advocates.

versus

THE DEPUTY CONTROLLER OF PATENTS AND DESIGNS .....Respondent

Through: Ms. Anubha Bhardwaj, CGSC with Ms. Ananya Shamshrey and Ms. Manavi Dhingra, Advocates.

CORAM:
HON'BLE MS. JUSTICE JYOTI SINGH

JUDGEMENT

JYOTI SINGH, J. (ORAL)

1. This appeal is filed on behalf of the Appellant under Section 117A of the Patents Act, 1970 ('1970 Act') challenging order dated 31.01.2020 passed by the Respondent refusing Indian Patent Application No. 3029/DELNP/2015 and for a direction to the Respondent to grant the patent.

2. To the extent necessary, the facts are that the subject invention relates to 'STABLE PRESERVATIVE-FREE MYDRIATIC AND ANTI-INFLAMMATORY SOLUTION FOR INJECTION'. Appellant filed a PCT International Application on 23.10.2013 bearing No. PCT/US2013/066349, claiming priority from US Application No. 61/718,026 dated 24.10.2012 and

US Application No. 61/736,179 dated 12.12.2012. Appellant filed Indian Patent Application No. 3029/DELNP/2015 on 10.04.2015 with complete specification comprising claims 1-27 and drawings.

3. It is stated in the appeal that Request for Examination by way of Form-18 was made on 27.05.2015 and Form-13 was filed on 02.07.2015 requesting to place on record amended set of claims 1-13 by way of correction and explanation. First Examination Report ('FER') was issued by the Respondent on 09.03.2018, to which Appellant filed a response on 07.12.2018 along with amended set of claims 1-9. Hearing was conducted on 25.09.2019, whereafter post-hearing written submissions were filed by the Appellant on 04.10.2019. On 31.01.2020, Respondent passed the impugned order and refused the application on ground of lack of inventive step under Section 2(1)(ja) of 1970 Act and non-patentability under Section 3(e).

4. Learned counsel for the Appellant submits that present invention relates to a stable, preservative-free and antioxidant-free liquid pharmaceutical formulation of Ketorolac and Phenylephrine for injection into intraocular ophthalmologic irrigation solutions. Claimed invention recites a sterile liquid pharmaceutical formulation comprising Phenylephrine, Ketorolac and a 20mM sodium citrate buffer system in an aqueous carrier, wherein the formulation is preservative free and antioxidant free, which is claim 1. Further, the formulation is a solution which is free of solubilizing agents and free of visible precipitation and crystallization and is stable for 6 months when stored at a temperature from 5+/-3° C to 25+/-2° C. The formulation can be suitably injected into an intraocular irrigation carrier and is used to irrigate ocular tissues during surgery. Additionally, this

formulation avoids the potential toxicity that may be associated with preservatives and antioxidants and still has stability.

5. It is submitted that present invention provides a solution to the problem as to how to maintain long-term stability for a liquid intracameral ophthalmic solution, which is a mixer of two disparate active pharmaceutical ingredients (APIs), one of which is a weak aromatic base (Phenylephrine) and one of which is a weak aromatic acid (Ketorolac) without use of either antioxidant or preservatives, that are typically required for stability but can be injurious to intracameral tissues. Therefore, the invention provides a sterile formulation of irrigation solutions for perioperative local application to ocular tissues, including intraocular and topical application, where Phenylephrine is used as a mydriatic agent and Ketorolac as an anti-inflammatory and both are free of preservatives and antioxidants and yet document unexpected good stability. They are preferably packaged in single-use containers for injection and can be injected into a larger volume of intraocular irrigation carrier prior to and during intraocular procedures such as Cataract extraction and lens replacement and refractive lens exchange procedures.

6. It is submitted that conventionally used mydriatic agents such as Phenylephrine with preservatives have been associated with a condition known as Toxic Anterior Segment Syndrome (TASS), which is widely regarded as a serious complication arising in ophthalmic surgeries and even in cases where mydriatic formulation is preservative free i.e., devoid of antimicrobial preservatives. Such formulations may nevertheless contain antioxidant agents, which are known to cause toxicity to the eye. Phenylephrine, particularly, is not approved in United States in a

preservative and antioxidant free form for single use injection. Post-operative pain and irrigation can be reduced by using NSAID, which again has limitation. Ketorolac, known to be a weak aromatic acid, is an NSAID i.e., commercially available for ocular use but may include Benzalkonium Chloride as a preservative. Conventional ocular formulations suffer from the drawback that therapeutic agents may be rapidly cleared due to blinking and the eye's natural circulatory processes. This may require repeated or large volume administration to maintain therapeutic efficacy. However, where such formulations include preservative or antioxidant agents, including formulations containing Phenylephrine and Ketorolac, the administration of larger volumes may be undesirable owing to associated risk of ocular toxicity, including TASS. Present invention is for a formulation comprising Phenylephrine and Ketorolac and 20mM sodium citrate buffer system, where formulation is preservative free and antioxidant free and stable.

7. It is urged that Respondent has wrongly refused the patent application and the impugned order suffers from grave errors on merits as also violations of principles of natural justice and is wholly unreasoned and non-speaking. While the impugned order rejects the application under Section 2(1)(ja), owing to prior arts D1-D3 as also 2(1)(j) and Section 3(e) but there is no reasoning to support the conclusions. There is no reason in the order as to why the experimental data provided in the complete specification was insufficient to establish patentability of the claimed invention. Appellant provided complete experimental data in the detailed description in the complete specification, which demonstrates that claim formulation is stable for more than 30 months as opposed to 6 months, where formulations include antioxidant or preservative. Respondent does note the presence of

stability data but holds that achieving stability of such pharmaceutical formulation without preservatives and antioxidants is not surprising at all and for coming to this conclusion, Respondent has given no reasoning as to how stability will be achieved in the absence of preservative and antioxidant. Further, Respondent not only ignores the conventional state-of-art, where such formulations have consistently included preservatives and antioxidants but also ignores the generally known nature of Phenylephrine, which is a weak aromatic base and Ketorolac, which is a weak aromatic acid. It is generally known that when combined the two would ordinarily be expected to undergo an acid-base reaction and this alone, combined with the single formulation, would give rise to credible and strong concerns regarding incompatibility and instability and would necessitate preservatives and/or antioxidants. There is not a shed of reasoning in the impugned order as to how stability will be achieved considering these aspects. In fact, while observing that a pharmaceutical formulation has certain stability, Respondent has ignored that in conventional compositions, stability was achieved only through use of preservatives and antioxidants.

8. It is submitted that Respondent has erred in concluding that amended claims 1-7 lack inventive step under Section 2(1)(ja) in view of prior arts D1-D3. Respondent has wrongly observed that the formulation claimed in the instant application, which contains Phenylephrine, Ketorolac and sodium citrate buffers and is preservative free and antioxidant free is disclosed in D1 and/or that D2 discloses buffer and pH of the solution and D3 discloses fluticasone formulation, which also contains Phenylephrine and/or that D3 also discloses about the stability of the solution. There is a manifest error in the observation that D3 may or may not contain preservative and therefore,

formulation disclosed in D3 may or may not contain a preservative. There is a glaring error in holding that composition which contains Phenylephrine, Ketorolac and sodium citrate buffers is well known to a person skilled in the art to combine the knowledge of cited prior arts D1-D3. A person skilled in the art would have certainly expected Phenylephrine and Ketorolac to be both unstable and incompatible together in a liquid concentrate for 6 months or longer. Chemical properties of Phenylephrine and Ketorolac would have discouraged a person skilled in the art from combining them in a liquid solution for extended storage. Phenylephrine is an organic weak base prone to oxidation and person skilled in the art would have expected that these two compounds, when combined in a solution, would undergo oxidative degradation even more rapidly. The prior art taught that Phenylephrine and Ketorolac salts i.e., cations and anions in solutions, were the most likely chemical compounds to undergo acid-based reaction and precipitate. A person skilled in the art would thus certainly have expected Phenylephrine and Ketorolac to be both unstable and incompatible together in a liquid concentrate for 6 months or longer. This aspect of present invention i.e., unexpected lack of physical incompatibility of the two APIs in a solution that not only does not include antioxidant and preservative but also does not include any solubilizing agents, is reflected in the amended claims of the instant application. With this backdrop, nothing in D1-D3 would have motivated a person skilled in the art to arrive at the claimed invention and hence, the entire analysis of lack of inventive step is manifestly incorrect.

9. It is further submitted that Respondent has failed to follow the five-step test laid down by the Division Bench of this Court in ***F.Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., 2015 SCC OnLine Del 13619***, for

determining the inventive step and obviousness. D1 relates to clinical study evaluating OMS302, described as a liquid drug product containing Phenylephrine and Ketorolac in a certain ratio with sodium citrate buffer. D1 discloses that OMS302 investigational drug product is free from particulates of foreign matter, which are distinct from precipitates or crystals of APIs and does not disclose that formulation is free of solubilizing agents and has no visible precipitates and crystals. Moreover, D1 does not disclose that formulation of Phenylephrine and Ketorolac is preservative and antioxidant free. D2 teaches converse of the instant application, which is the preferred use of antioxidants. It also discloses that to ensure stability a standard ophthalmic irrigation solution should be mixed just prior to use, which means that such solutions will not be stable for any extended period prior to use. D3 discloses an ophthalmic formulation of fluticasone, however, this is a corticosteroid and has no relevance to the instant formulations of Ketorolac and Phenylephrine. In light of these prior arts, it is not understood how even remotely person skilled in the art would arrive at the claimed invention.

10. Rejection under Section 3(e), submits learned counsel, is equally untenable for the reason that there is no reasoning to come to the conclusion. Respondent has in one line upheld the ground of non-patentability stating that instant claims do not pass the test of Section 3(e) in the absence of any surprising or synergistic effect. Prior arts recognize that use of preservatives and antioxidant agents in mydriatic formulations employed for pupil dilation were associated with corneal toxicity and related adverse effects. In this background, the claimed formulation comprising Phenylephrine and Ketorolac provides a synergistic effect by simultaneously maintaining

formulation stability and preventing clinically meaningful miosis and reducing the likelihood of toxicity associated with post-operative ophthalmic procedures.

11. Ms. Anubha Bhardwaj, learned CGSC appearing on behalf of the Respondent submits that the instant application has been rightly refused for lack of inventive step, lack of technical feature and non-patentability under Section 3(e). Combination of Phenylephrine, Ketorolac and sodium citrate buffer, all known substances individually disclosed in prior arts D1-D3 do not result in a composition exhibiting any technical advancement or unexpected synergistic effect. D1 discloses composition for intraocular use comprising Phenylephrine and Ketorolac tromethamine in sodium citrate buffer. D2 and D3 further support the knowledge of using such combinations in aqueous solutions for ophthalmic purposes. D2 also discloses the buffering agent. Technical challenge of formulating a preservative free and antioxidant free combination with stability is not non-obvious, especially since D3 already suggests preservatives are not essential. D3 also exemplifies a formulation, which is antioxidant free. No comparative data was filed by the Appellant to show any improvement over the prior arts or to demonstrate enhancement of efficacy and hence, the claimed invention lacks inventive step.

12. It is submitted that claims 1 and 3 describe stability at specific temperature ranges. Such a statement is a result to be achieved and not technical feature of the formulation. Specification lacks sufficient disclosure as to how such stability is technically ensured without preservatives or antioxidants. Claimed formulation is mere admixture of known components, each performing its well understood function. Ethanol (solvent), sodium

citrate (buffer), Phenylephrine (mydriatic) and Ketorolac (NSAID) are individually known and no data or comparative study was provided to demonstrate synergistic effect. Thus, there is no infirmity in the impugned order warranting interference.

13. Heard learned counsels for the parties and examined their submissions.

14. Appellant filed the instant application on 10.04.2015 with complete specification comprising claims 1-27 with drawings. FER was issued on 09.03.2018 objecting to the invention on grounds of lack of inventive step, lack of technical features and non-patentability under Section 3(e). Five prior arts D1-D5 were cited to support lack of inventive step. Appellant filed response to FER pointing out that at the time of receipt of FER, claims 1-13 were pending and Appellant had suitably amended the pending claims and only claims 1-9 remained pending. Prior arts were sought to be distinguished by detailed narrative in the reply, to bring home the point that the claimed invention did not lack inventive step as none of the cited prior arts taught or suggested or motivated the subject matter of the claimed invention, which was thus non-obvious to a person skilled in the art to be able to arrive at the invention. Response was also given to the objection under Section 3(e) and Section 2(1)(j), asserting that none of these objections were made out, however, the application was refused.

15. Claimed invention relates to stable, preservation-free and antioxidant-free pharmaceutical formulation intended for use in ophthalmic surgery, more particularly, pupil dilation (mydriasis), which is required during ophthalmic surgical procedures and is conventionally achieved through pre-operative topical administration of a mydriatic agent. Respondent has

refused the application on three grounds: lack of inventive step; lack of technical features; and non-patentability under Section 3(e) due to lack of synergistic effect. D1-D3 have been taken as prior arts in the impugned order to refuse the application for lacking inventive step. From the order, it is apparent that substantial part of the order focuses on referring to the disclosures/teachings in D1-D3. One paragraph is dedicated to the findings and the conclusion that the claims in the instant application do not involve an inventive step as being obvious over the teachings of D1-D3. In coming to this conclusion, Respondent holds that composition, which contains Phenylephrine, Ketorolac and sodium citrate buffer, is well known to the person skilled in the art and further that it will be obvious to such a person to maneuver all components as needed as a matter of judicious selection. It is observed that Phenylephrine is a mydriatic agent and Ketorolac is a NSAID drug and use of buffer for maintaining the pH of formulation is known from D1. D2 and D3 are actually further work to find out more suitable pharmaceutical formulation and hence, it is within the ambit of a skilled artisan to try some more suitable formulations by combining D1, D2 and D3 and arrive at the subject invention. It is further observed that Appellant has provided comparative stability data in the specification, wherein stability of various formulations have been presented, with and without preservative and antioxidant and Appellant tries to solve the problem of how to maintain long-term stability without use of either the preservative or the antioxidant but in view of D1-D3, stability is not surprising but is obvious and that claimed stability of the formulation is an inherent property in the formulation disclosed in the prior arts.

16. Having carefully perused the impugned order, this Court finds merit

in the contention of the Appellant that the order is not only unreasoned but also violative of the directions passed by the Division Bench of this Court in ***F.Hoffmann (supra)*** to follow a five-step test to determine whether the claimed invention has or lacks inventive step. The five steps elucidated by the Division Bench are as follows:-

> Step No. 1 - To identify an ordinary person skilled in the art;
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> Step No. 2 - To identify the inventive concept embodied in the patent;
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> Step No. 3 - To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date;
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> Step No. 4 - To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications; and
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> Step No. 5 - To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art and rule out hindsight approach.

17. As the response to FER and post-hearing written submissions indicate, Appellant had laboured hard to point out what in its perception were stark differences in the prior arts and the claimed invention but none of these points have been considered by the Respondent. To begin with, Respondent has overlooked that according to the Appellant, the experimental data, which was admittedly provided in the detailed

description, does demonstrate that the claimed formulation with Ketorolac, Phenylephrine and sodium citrate buffer is stable for more than 30 months without preservative and antioxidant, as opposed to a period of 6 months even where preservatives and antioxidants are included. No part of the order deals with this submission, which is a crucial point in relation to the claimed invention. Respondent observes that achieving stability of pharmaceutical formulation without preservative and antioxidant is not surprising but there is no reasoning on how extended stability could be achieved in the absence of preservative and antioxidants. Respondent has also not dealt with the stand of the Appellant that conventional state-of-art formulations have consistently included preservatives and antioxidants and that Phenylephrine being a weak aromatic base and Ketorolac being a weak aromatic acid, when combined will ordinarily undergo an acid-base reaction and this alone, combined with a single formulation, would give rise to credible and strong concerns regarding incompatibility and instability and would necessitate preservatives and/or antioxidants. In such a backdrop, how stability will be achievable, is not explained in the order.

18. Learned counsel has shown that Respondent has not given an iota of reason to disregard the response of the Appellant that combination of Phenylephrine and Ketorolac would not be obvious to the person skilled in the art, who would certainly have expected them to be both unstable and incompatible together in a liquid concentrate for 6 months or longer and chemical properties of both Phenylephrine and Ketorolac would discourage a person skilled in the art to combine them in a liquid solution for extended storage. Both Phenylephrine and Ketorolac are known to be prone to oxidation and contrary to the finding of the Respondent, in fact, a person

skilled in the art would have expected that if combined in a solution, Ketorolac and Phenylephrine would undergo oxidative degradation even more rapidly. There is absolutely no analysis on this stand of the Appellant by the Respondent. Appellant is right that Respondent ought to have dealt with this issue as also the points flagged by the Appellant that Phenylephrine was not approved for sale in US as a preservative/antioxidant free form. Respondent has also not considered the differences brought forth by the Appellant that D1 fails to specifically describe a formulation which is free of preservative/antioxidant and D2 *albeit* describes a composition of Phenylephrine and Ketorolac but specifically describes use of antioxidant as also that D3 is corticosteroid and has no bearing on the instant formulation. In my view, Respondent was under an obligation to consider the points raised by the Appellant in response to the objections raised and also follow the five-step test while determining lack of inventive step. Court also finds that there is no reasoning for refusing the application under Section 3(e) and all that is stated in the impugned order in one line is that in the absence of any surprising or synergistic effect, the instant application does not pass the test of Section 3(e). Courts have consistently held that reasons must accompany every decision and many cases have been remanded to the Controller only on the ground of unreasoned orders. Yet the orders continue to be non-speaking and unreasoned and to compound, the orders do not even reflect consideration of the points raised by a patent applicant, both factual and legal, be it in response to the FER or in the detailed written submissions. The result is that the purpose of seeking response to FER and/or permitting filing of post-hearing written submissions is defeated and is reduced to a mere formality. Consequence is that Courts have to remand the matters and

the already long procedure of grant of patent becomes longer.

19. For all the aforesaid reasons, the impugned order dated 31.01.2020 is set aside and the matter is remanded to the Respondent for fresh consideration of Indian Patent Application No. 3029/DELNP/2015. Respondent shall take a decision within four months from today after granting opportunity of hearing to the Appellant and considering the detailed response to the FER as also the written submissions. Needless to state that the order will be a speaking and reasoned order. It is made clear that Court has not expressed any opinion on the merits of the case.

20. Appeal is partially allowed and disposed of.

JYOTI SINGH, J

MAY 15, 2026/YA