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

Date of Decision: 12th July, 2022

\+ **C.A. (COMM.IPD-PAT) 295/2022 & I.As.10369-70/2022**

BOEHRINGER INGELHEIM INTERNATIONAL GMBH ..... Appellant

Through: Mr. Debashish Banerjee and Mr. Ankush Verma, Advs. (M:9810948290)

versus

THE CONTROLLER OF PATENTS & ANR. ..... Respondents

Through: Mr. Harish Vaidyanathan Shankar, CGSC with Mr. Srish Kumar Mishra, Mr. Sagar Mehlawat and Mr. Alexander Mathai Paikaday, Advocates. (M:7204711976)

CORAM:
JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J. (Oral)

1. The present appeal arises out of the impugned order dated 25th March, 2022 by which the Controller of Patents (*hereinafter "Controller"*) has rejected the request of the Appellant-Applicant (*hereinafter "Applicant"*) for pursuing a divisional application bearing no.20178031279 dated 4th September, 2017, titled *'A medicament of a DPP inhibitor'*. The Controller, while rejecting the divisional application has stated that the divisional application had similar claims, as had already been proffered in the refused amendment applications and the divisional application does not fall within the scope of the parent application.

Factual background

2. The background of this appeal is that the Applicant had filed a National Phase PCT Application on 14th November, 2008, for ***'Use of DPP***

IV Inhibitors'. The patent specification had a total of 1 to 18 Claims, with two claims numbered as 15. For the sake of clarity, the same are re-numbered as 15 and 15A at the outset. The First Examination Report (*hereinafter "FER"*) was issued on 24th March, 2014, in response to which the Applicant amended its Claims on 24th October, 2014 *(hereinafter "Amendment No.1")*. In the said Amendment No.1, the Applicant sought to delete all Claims except Claims 14, 15 & 15A.

3. Thereafter, the application remained pending. Sometime in 2015-2016 i.e., on 20th March, 2015 and 18th February, 2016, two Forms-13 were filed by the Applicant seeking two further amendments (*hereinafter "Amendment No.2" and "Amendment No.3" respectively*). These two amendments were, thereafter, sought to be converted into a divisional application filed on 4th September, 2017. This application has been rejected by the impugned order.

4. In Amendment No.2 dated 20th March, 2015, the Applicant sought to expand from three Claims to Claims 1 - 11 and in Amendment No.3 dated 18th February, 2016, the Applicant amended the Claims to 1 to 15, i.e., added four new Claims. On 5th July, 2017, a hearing notice was issued by the Patent Office and the following objections were raised:

> *"2. The examination report is based on the claims filed on 24/10/2014 as form-13 filed on 23/02/2015 and 19/02/2016 not allowed as amendments carried out in claims, via said forms, goes beyond the scope of claims as on record before the amendments.*
>
> *Claims 1-3 lack novelty and inventive step under section 2(1)(j) of Patents Act,1970. The following documents are considered for the examination.*
>
> *D1: WO 2004/018468 A (2004-03-04)*

D2: WO 2004/050658 A (2004-06-17)

D3: WO 2005/085246 A (2005-09-15)

D4: WO 2006/029769 A (2006-03-23)

Novelty under section 2(1)(j) of Patents Act,1970.

D1, D2, D3 and D4 discloses the use of specific DPP-IV inhibitors which in each case fall under the Markush formula of the present application, for the treatment of, inter alia, diabetes mellitus type 1 and type 2, prediabetes, reduction of the glucose tolerance or changes in the fasting blood sugar, diabetic complications, insulin resistance, metabolic syndrome or dyslipidaemia. The use of the DPP-IV inhibitors as combination medicament with other antidiabetics (including metformin), with antilipemics (including atorvastatin) or with agents which lower blood pressure is also disclosed.

So novelty cannot be acknowledged for the present set of claims 1-3

Inventive step under section 2(1)(ja) of Patents Act,1970.

Each of the documents D1-D4 represents per se the closest prior art, since the use of specific DPP-IV inhibitors for the treatment of diabetes mellitus in various facets is disclosed and it appears that there is no technical advancement achieved with the compounds of the present application with respect to its closest prior art documents.

Claims 1-3 don't contain any technical feature except DPP inhibitors which is already known from the above-cited documents D1-D4.

So inventive step cannot be acknowledged for the present set of claims 1-3."

5. The objections in the FER included lack of novelty and inventive step. Pursuant to this hearing notice, the objections raised were contested by the Applicant. The hearing on the objections was held in August, 2017. The decision on the said parent application and the Amendments was rendered finally in January, 2018.

6. Notably, after the hearing on the Amendments to the original patent application was held on 28th August, 2017 and prior to rendering of the decision on 4th January, 2018, the Applicant sought to file a divisional application on 4th September, 2017 by creating an amalgam of Claims 1 to 11 and Claims 1 to 15, which Claims also formed part of Amendment Nos. 2&3.

7. The Controller vide decision dated 4th January, 2018, passed the decision on all three Amendments. Insofar as Amendment No.1 restricting the original patent to Claims 14, 15 & 15A is concerned, a decision was rendered on merits. Insofar as Amendment Nos. 2&3 are concerned, the Controller held as under:

> *"Subsequent to FER reply two form-13 filed on 23/03/2015 and 19/02/2016 for making amendment in claims. The amended claims 1-11 as filed on 23/03/2015 relates to a medicament combination of a DIPP IV inhibitor with metformin and the amended claims as filed on 19/02/2016 further contains 4 new claims (claims 12-15), in addition to claims as filed on 23/03/2015, which relate to a medicament combination of a DIPP IV inhibitor with telmisartan.*
> *The scope of protection of original filed claims, i.e. use of DPP IV inhibitor of formula I or formula II alone or in combination with other active substances, cannot be extended to the protection of a medicament combination of a DIPP IV inhibitor with metformin/telmisartan as such such change in contents*

> *of amended claims* ***does not wholly fall within the scope of original filed claims****. Further said amendments cannot be considered to be done by way of disclaimer, correction, clarification or explanation as there is clear change in category of claims wherein "use claims" were amended to "product claims".*
>
> …
>
> *Based on the above facts and circumstances of the case, it is observed that the objections raised in paragraphs 2 and 3 the hearing notice are still pending and not met. Therefore, the instant application No. 09501/DELNP/2008 is hereby refused for grant of patent u/s 15 of the Patents Act, 1970."*

8. Thus, the Controller applied Section 59 of the Patents Act, 1970 (*hereinafter "the Act"*) and held that the said amended claims i.e., Claims 1 to 11 and Claims 1 to 15 are beyond the scope of originally filed Claims and rejected the same. Accordingly, vide this order dated 4th January, 2018, the Patent Application 9501/DELNP/2008 which was the parent application, was refused under Section 15 of the Act. Amendment Nos. 2&3 were also rejected by the Controller, but by the time this order was passed, the Applicant had filed a divisional application *qua* those very claims.

9. After this decision was rendered, in so far as the pending divisional application was concerned, the FER was issued on 16th July, 2019. A response dated 16th January, 2020 was filed to the said FER and a pre-grant opposition dated 27th January, 2021, was also filed *qua* this divisional application. The reply statements, etc. were completed in the pre-grant opposition and after hearing the pre-grant opponent and the Applicant, by the impugned order dated 25th March, 2022, the divisional application was refused. The reasoning given by the Controller in the impugned decision is that the division itself could not have been permitted as the Amendments

were rejected in the parent application. Since the current Claims had been already examined and refused, the same Claims cannot be allowed in another application. The Controller also reproduced various other objections raised by the pre-grant opponent. The findings in the impugned order dated 25th March, 2022 are as under:

> *"c) I have analysed the amended claims of the parent application (9501/DELNP/2008) were refused under section 15 due to the reason that none compliance of section 57 and 59. As well as the parent refusal order clearly indicates the lack of Novelty and inventive step as well.*
>
> *The applicant replicated amended claims of the parent application in the Divisional application (present), since, there were three set of claims was filed/amended until refusal of the parent application, the first set was original claims (18 claims) and second set of claims (11 claims) amended in the year 2015 in response to FER and the third set of claims (15 claims in 2016) all above three set of claims have been examined, finally an opportunity of hearing was also offered followed by written submission, based on argument and /or written submissions, the refusal order was issued in the parent application refusing all the claims. The three set of claims are distinguished as under in tabular format to make it clear understanding, and all three set of claims are reproduced above.*

Claims of present application (201718031279)	**Exactly similar Claims of parent application9501/DELNP/2008**	**Remarks**
Claims 1, 2	Claims 1, 2 Amended dt.25/03/2015	Exactly similar claims have been examined in Parent application

Claims 3, 4	Claims 3, 4	Exactly similar claims have been examined in Parent application
Claims 5,6,7,8	Claims 5,6,7,8	Exactly similar claims have been examined in Parent application
Claim 9, 10	Refer claims 5 to 8	Exactly similar claims have been examined in Parent application
Claim 11	Claim 7, 11	Exactly similar claims have been examined in Parent application
Claim 12, 13	Covered under claims 7-11	Exactly similar claims have been examined in Parent application
Claim 14,15	Covered under claims 5 & 2	Exactly similar claims have been examined in Parent application
Claim 16, 17	Covered under claims 14 of new claims in 2016 , and 12 claim in 201515,	Exactly similar claims have been examined in Parent application
Claim 13 (Method claims)	Claim 18, examined in 2015 and 2016 of claims 7 to 13	Only wordings rearranged no changes in technical parameters
Claim 20	Claim 5 of 2015	Exactly similar claims have

		been examined in Parent application
Claims 24 and 25		repetitions of the old parent application claims

From the above analysis, it is observed that the claims amended at various point of time during prosecution of the parent application which are exactly similar to that of present claims pending with alleged divisional patent application.

d) It is to be noted that the claims which are amended in the Parent application for grant of patent, at various stages that includes in response to First Examination report, in response to hearing notice and as well in post hearing written submission as well. Those claims were refused with a due process under section 15. The reason for refusal can be seen in the order of parent application, however, the applicant submitted before the hearing officer that previous amendments carried out in the claims on March 23, 2015 and February 19, 2016 are allowable. The amendments made in claims were based on original claims 10-12 and the description in the specification and are therefore allowable under Section 59(1) of Act. In this regard, the attention is invited to last paragraph page 12, which reads as 'The DPP IV inhibitors mentioned above may also be used in conjunction with other active substances, by means of which improved treatment results can be obtained Such a combined treatment may be given as a free combination of the substances or in the form of a fixed combination, for example in a tablet or capsule. Paragraph 2 of page 13 reads as Examples of antidiabetic combination partners are metformin. The last paragraph of page 20 reads 'A particular preferred example of an antidiabetic combination partner is metformin. The last paragraph of page 22 recites telmisartan as a combination partner. Further, Examples 13 and 16 of the specification relate

to combinations with metformin and telmisartan respectively.

The learned Controller's attention is further invited to the provisions under Section 59 of the Act which lays down the conditions for allowance/disallowance of amendments. Section 59 is reproduced below:

Section 59(1)- No amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment. Under Section 59(1), the amendments made by the Appellant should not fall outside the scope of the unamended specification. This has also been affirmed by the Honorable Board in its order Solvay Fluor GmBH v E.l Du Pont de Nemours and Company & others (ORDER No.111 of 2010). The relevant paragraphs 18 and 19 of the order are reproduced below:

18. We have heard the arguments of both the counsel and have gone through the petitions and the replies filed thereon. The amendments suggested must comply with the requirements of section 59 of the Act. 19. Hence from the above section 59 of the Act, what are permissible amendments are as follows:- 1. Amendment must be by way disclaimer, correction, clarification or explanation; 2. The amendment must be for incorporation of actual fact; 3. The effect of amendment should not enable the specification as amended to describe any matter not in substance disclosed or shown in the specification before amendment; All the three above-identified conditions are

fulfilled by the amended claims submitted by the Applicant in the present application.

The amendments were carried out by way of correction and explanation. Further, as the medicament combinations are clearly disclosed in the specification, the amendments pertained to incorporation of actual fact. The third condition was also complied with since the amendments made by the Appellant pertain to the matter already disclosed in the specification and do not fall outside the scope of the unamended specification. In view of the above, it was requested to allow the amendments carried out on March 23, 2015 and February 19, 2016.

e) The Applicant submits that the amended claims are novel and inventive over the cited prior art documents and do not fall under Section 3(e). In this regard, the Applicant submits the following: Beneficially, as stated in the application was filed, the DPP IV inhibitors as included in the present claim set "are distinguished from structurally comparable DPP IV inhibitors, as they combine exceptional potency and a long-lasting effect with favourable pharmacological properties, receptor selectivity and a favourable side-effect profile or bring about unexpected therapeutic advantages or improvements when combined with other pharmaceutical active substances" (page 11 of the description). Linagliptin (BI 1356), a particularly preferred DPP-4 inhibitor of the present application (page 7 of the description, last paragraph, first species) inhibits DPP-4 more effective and longer lasting than the other major DPP-4 inhibitors vildagliptin, sitagliptin, saxagliptin and alogliptin, and is thus potent at low therapeutic doses and long-acting. The low dose amount is a particular feature for the provision of combinations of the present DPP IV inhibitor species according to the present claim set, constituting a contribution of the invention over the art. The low oral dose such as recited in the claims reflects said exceptional potency and long lasting effect, and is for at least this reason remarkable and valuably

enriching the art. Further, Linagliptin is characterized by unique pharmacokinetics, such as with nonlinear profile (less than dose-proportional exposures). Other gliptins have dose-proportional (fairly linear) oral pharmacokinetie properties. Accordingly, optimization for therapeutic dose of linagliptin is not necessarily trivial. Further beneficially, the combination of linagliptin and metformin was shown to be well tolerated and improved glycemic control more than either monotherapy. For example: Combination of linagliptin and metformin improves glycemic control in type 2 diabetes: A randomized trial with an open-label arm in patients with poor glycemic control: Progression to combination of oral glucose-lowering drugs in patients with type 2 diabetes mellitus (T2DM) is recommended when monotherapy fails to reach treatment targets. This 24-week, double-blind, placebo controlled study randomized 791 T2DM patients. The 6 treatment groups included 2 arms receiving free combinations of linagliptin 2.5 mg bid+ either low- or high-dose (500 or 1000 mg) metformin (MET) bid.

Four monotherapy arms received linagliptin 5 mg q,d, MET 500 or 1000 mg bid, or placebo. Patients with a baseline HbAIc ≥11% received open-label combination therapy with linagliptin 2.5 mg bid+ MET 1000 mg bid (n=66). Mean baseline HbA1c was between 8.5% and 8.7%, and 11.8% in the open-label arm. Placebo-corrected, adjusted mean HbAIc changes after 24 weeks are shown in the figure [figure 1]. For the combination of linagliptin 2.5 +MET 500 or 1000, the placebo corrected reduction in HbAIc was -1.3% and -1.7%, respectively. Both combination regimens were superior to the monotherapy arms. In patients with poor glycemic control, mean change in HbA1c from baseline was -3.7%. Adverse event rates were similar across treatment arms. The total number of hypoglycemic events during combination treatment was low (in total, 5 [1.8%] randomized patients receiving linagliptin 2.5 + MET 500 or 1000). The difference in body weight after treatment

with linagliptin 2.5 +MET 1000 compared with MET 1000 was -0.23 kg. The combination of linagliptin and MET was well tolerated and improved glycemic control more than either monotherapy. Combination of linagliptin with MET significantly improves glycemic control towards treatment targets without weight gain and with a very low risk of hypoglycaemia Figure 1, Therefore, e.g., a particularly suitable and beneficial/positive therapeutic combining effect and usability (e.g. significant efficacy and/or favourable safety) can be achieved by the combinations according to the present invention, thus valuably enriching the art. The above Figure 1 clearly shows the effects of linagliptin (5 qd) alone, metformin (500 bid, 1000 bid) alone, as well as the effects of various linagliptin+metforrnin combinations, particularly the considerable effect in the most right bar in Figure 1 as to the combination linagliptin+metformin in patients with poor glycemic control. The combination of linagliptin and metformin provides significant improvements in glycemic control compared to placebo, to metformin alone, and to linagliptin alone. Thus, the combination therapy of linagliptin with metformin relates to a particular embodiment of the present invention. Furthermore beneficially, in type II diabetes patients who are not adequately controlled on another oral anti-hyperglycemic drug, the combination of a DPP-IV inhibitor of this invention with such other anti-hyperglycemic drug provides a therapeutic benefit to such patients. Especially, in type II diabetes patients who are not adequately controlled on metformin, the add-on combination of linagliptin (which is a DPP-IV inhibitor of this invention) to existing metformin therapy results in a significant and clinically meaningful improvement in glycemic control, without weight gain or increased risk of hypoglycemia; thus such combination provides indeed a "synergistic" (cooperative, complementary or improving) effect. One skilled in the art would not have plainly and inevitably predicted that the specific dosage amount of the DPP-IV inhibitor species in a combination

with metformin would provide the (clinically and therapeutically) significant improvements in glycemic control (AI C and FPG) as outlined above.

f) With reference to paragraph 2 of the hearing notice the agent for the applicant submitted that the amendments previously carried out in the claims on March 23, 2015 and February 19, 2016 are not found to be persuasive as amended claims so filed goes beyond the scope of originally filed claims. It may be noted that the subject matter of originally filed claims relate to USE of DPP IV inhibitor of formula I or formula II alone (claims 1-9) or in combination with other active substances (claims 10- 13), isolation or storage medium for islets of Langerhans or beta cells (claims 14-15), method of enhancing the vitality and secretion capacity of islets of Langerhans or beta cells and method of treating a patient with a DIPP IV inhibitor (claims 16-18).

The said claims were restricted to three claims relating to isolation or storage medium for islets of Langerhans or beta cells and method of enhancing the vitality and secretion capacity of islets of Langerhans or beta cells in response to FER filed on 24/10/2014. Subsequent to FER reply two form-13 filed on 23/03/2015 and 19/02/2016 for making amendment in claims.

g) The amended claims 1-11 as filed on 23/03/2015 (are most similar to the present patent application) "relates to a medicament combination of a DIPP IV inhibitor with metformin and the amended claims as filed on 19/02/2016 (are most similar to the present patent application) further contains 4 new claims (claims 12-15), in addition to claims as filed on 23/03/2015, which relate to a medicament combination of a DIPP IV inhibitor with telmisartan. The scope of protection of original filed claims, i.e. use of DPP IV inhibitor of formula I or formula II alone or in combination with other active substances, cannot be extended to the protection of a medicament combination of a DIPP IV

inhibitor with metformin/telmisartan as such change in contents of amended claims does not wholly fall within the scope of original filed claims. Further said amendments cannot be considered to be done by way of disclaimer, correction, clarification or explanation as there is clear change in category of claims wherein "use claims" were amended to "product claims" entirely changes in the scope. The submission given by the agent for the applicant w.r.t. section 3(e) of the Patents Act is in reference to the amended claims, relating to medicament combination, which were not allowed hence said submission is irrelevant. Further no submission filed by the agent for the applicant for the objections raised in paragraphs 2 and 3 of hearing notice, regarding lack of novelty and inventive step of claims 1-3 (as filed on 24/10/2014) w.r.t. cited prior art documents D1-D4 and claims 1-3 falling under section 3(e), 3(i) and 3(j) of the Patents Act, therefore said objections still stands. Based on the above facts and circumstances of the case, the parent application application No. 9501/DELNP/was refused for grant of patent u/s 15 of the Patents Act, 1970 as per as the parent application concerned.

h) The above analysis made on the original claims as well as on amended claims affected in 2015 and 2016 itself. Consequently the refusal order issued on the amended claims, and the refused claims are most similar with pending claims in the alleged patent application. It is to be noted that the parent refusal order clearly stipulates the reasons that the amended claims how it goes beyond the scope of the invention under section 57 and 59, and the amended claims subsequently were not allowed.

i) Because of non – allowance of the amended claims followed by refusal under section 15 would not be a case for divisional application. Perhaps, the amended claims could have been allowed in the parent application itself even If there was any little chance for allowance, The order also clearly indicates original and amended claims lacking Novelty and obviousness, regarding Novelty and

*inventive step the Parent refusal order has already been considered and examined during prosecution of the parent application. Thus, the current claims on record absolutely do not have any merits for the purpose of divisional application**. The entire specification directed for use of the compound, but nowhere in the specification relates to the medicaments.** The agent of the applicant made attempts to get a patent on the amended claims in the parent application, after refusal of the parent application claims (original, amended claims in 2015, amended claims in 2016) the three set of claims are similar to the present divisional application claims. **Therefore, failure to get patent on the parent application is not eligible criteria for divisional application. Very important to note that in case, if the amended claims are allowable in the present application then the same claims could have been allowed in the parent application itself if meeting all criteria.***

Therefore, the objection raised in the hearing notice i.e Invention u/s 2(1)(j) 1. Objections as mentioned in this office communication letter dated on 16/07/2019 is still maintained and applicant reply to objections on 31/12/2019 have been fully considered but they are not persuasive in view of the following reasons. Applicant argument that Section 16{1} clearly and expressly allows at any time before grant to voluntarily to file a divisional application in respect of any invention disclosed in the complete specification. But Section 16{1} of the Act illustrates that an applicant can file for a further application, if the complete specification related to more than one invention. Before the grant of patent that has been already been filled for which is referred to as the first mentioned application. "If he so desires" is not unconditional and it does not give the applicant an unjustified liberty to file a divisional application even when there is no multiple invention in the parent application. A divisional has to satisfy the test of Section 16 of the Act which means that more than one invention

in the parent application has to be shown. 1. Claims of the parent application 9501/delnp/2008 filed on 14/11/2008 did not contain any plurality of invention u/s 10(5) of the patent act 1970. Therefore the current divisional application is invalid and the current application is not allowed u/s 16(1) of the patent act 1970. Thus novelty and inventive step of the current divisional application is not examined.

Claims 1-25 of the current divisional application were already examined and refused in the parent application, and therefore same claims cannot be allowed in another application.

The above objection exhaustively discussed during the course of hearing followed by analysis of post hearing written submission made, the findings of the case are clearly enumerated above, in view of above findings the patent application bearing no. 201718031279 divisional of a refused PCT National Phase Application No.: 9501/DELNP/2008 95 is refused under section 15."

10. The present appeal challenges the above impugned order.

Submissions

11. At the outset, Mr. Banerjee, ld. counsel for the Applicant, submits that in the Amendments, which were sought in 2015 and 2016, i.e., Amendment Nos. 2&3, the Applicant's claims were for various medicaments of DPP IV Inhibitors, which were disclosed in the original National Phase PCT application. Thus, they were within the scope of the parent application.

12. As for the divisional application, ld. Counsel for the Applicant submits that Claims 1 to 25 are clearly based out of the original specification and thus, since the scope of the parent specification includes

the claimed products and formulations, the same can be the subject matter of the divisional application in terms of the Section 16 of the Act.

13. He further relies upon the judgement of the IPAB in ***Milliken & Company v. Union of India [OA/61/2012/PT/MUM, decided on 5th January, 2016]*** to argue that in the said case, the rejection of the second divisional application was set aside by applying Section 16 of the Act and holding that the applicant has a right to divide the inventions into separate divisional applications. He submits that the fact situation in the present case is similar, inasmuch as in ***Milliken (supra)***, in the first divisional application, Form 13 was filed seeking amendments and after the amendment was refused, a second divisional application was filed and was permitted.

14. On the other hand, Mr. Harish Vaidyanathan, ld. CGSC appearing for the Controller, submits that the impugned order does not deserve to be interfered with, inasmuch as the parent application, was for use of DPP IV inhibitors and not for the inhibitor/medicament itself. The manner in which the Amendments were sought to be made for seeking exclusivity *qua* the inhibitor was contrary to Section 10(4) of the Act. Once the Amendments were refused as being beyond the scope of claims, Section 16 of the Act cannot be invoked by the Applicant for filing a divisional application for the same claims. He further seeks to distinguish ***Milliken (supra)*** by holding that in the said case, the Controller himself had raised an objection that there was a plurality of inventions and multiple independently worded claims in the parent application, which was not allowable, as they fall beyond the scope of the main claims. Hence, the division was allowed in a completely different fact situation.

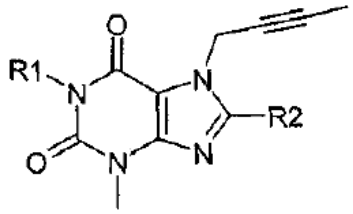
15. In response, Mr. Banerjee, ld. Counsel seeks to distinguish paragraph 16 of ***Milliken (supra)*** on the ground that the said paragraph deals with the parent application and not the relationship between the first divisional and the second divisional applications, whereas the issue in that matter concerns only the first and second divisional applications.

Findings and Analysis

16. Heard ld. counsels for the parties.

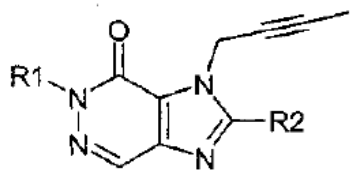
17. The present appeal is a case where the patent Applicant is seeking to file a divisional application to claim a monopoly in respect of DPP IV Inhibitors, which were originally not claimed in the parent application at all. A perusal of the Claims in the parent application shows that all Claims including Claim 1 which is the main claim, relate to *'Uses of DPP IV inhibitors'* of formula 1 or formula 2 along with certain substitutions at R1 and R2. The said original Claims illustratively, are demonstrated as below:

*"1**. Use of a DPP IV inhibitor** of formula (I)*



(I)

or of formula (II)



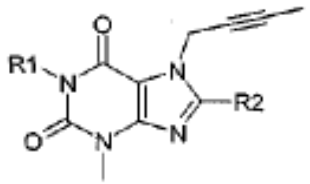
(II)

and one of the salts thereof, characterised in that

R1 denotes ([1,5]naphthyridin-2-yl)methyl, (quinazolin-2-yl)methyl], (quinoxalin-6-yl)methyl, (4-methyl-quinazolin-2-yl)methyl, 2-cyano-benzyl, (3-cyanoquinolin-2-yl)methyl, (3-cyano-pyridin-2-yl)methyl, (4-methyl-pyrimidin-2-yl)methyl, or (4,6-dimethyl-pyrimidin-2-yl)methyl and R2 denotes 3-(R)-amino-piperidin-1-yl, (2-amino-2-methyl-propyl)-methylaminoor(2-(S)-amino-propyl)-methylamino,

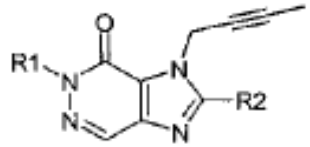
for preparing a medicament for the therapeutic treatment of a patient who has been diagnosed with a physiological functional disorder selected from among pre-diabetes, glucose intolerance, pathological fasting glucose, diabetic foot, diabetes-associated ulcer, diabetic hyperlipidaemia, diabetic dyslipidaemia, newly diagnosed type 1 diabetes, gestational diabetes, hyperglycaemia, adrenergic postprandial syndrome and heart failure, or for the therapeutic treatment of a patient with transplanted islets of Langerhans or beta cells.

2. ***Use of a DPP IV inhibitor*** *of formula (I)*



(I)

or of formula (II)



(II)

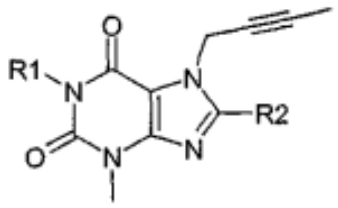
and one of the salts thereof, characterised in that R1 denotes ([1,5]naphthyridin-2-yl)methyl, (quinazolin-2-yl)methyl, (quinoxalin-6-yl)methyl, (4-methyl-quinazolin-2-yl)methyl, 2-cyano-benzyl,

(3-cyanoquinolin-2-yl)methyl, (3-cyano-pyridin-2-yl)methyl, (4-methyl-pyrimidin-2-yl)methyl, or (4,6-dimethyl-pyrimidin-2-yl)methyl and R2 denotes 3-(R)-amino-piperidin-1-yl, (2-amino-2-methyl-propyl)-methylaminoor(2-(S)-amino-propyl)-methylamino

for preparing a medicament for the treatment of patients who have been diagnosed with pre-diabetes or manifest type 2 diabetes, characterised in that by using the pharmaceutical composition the risk of impaired glucose metabolism despite treatment, an elevated HbA1c value despite treatment, an impaired fasting glucose value despite treatment, the need for insulin treatment, manifest type 2 diabetes, a diabetic foot, a diabetes-associated ulcer, diabetic hyperlipidaemia, diabetic dyslipidaemia or a macrovascular complication is reduced.

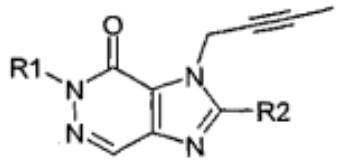
…

10. ***Use of a DPP IV inhibitor of formula*** *(I)*



(I)

or of formula (II)



(II)

and one of the salts thereof, characterised in that

R1 denotes ([1,5]naphthyridin-2-yl)methyl, (quinazolin-2-yl)methyl, (quinoxalin-6-yl)methyl,

(4-methyl-quinazolin-2-yl)methyl, 2-cyano-benzyl, (3-cyanoquinolin-2-yl)methyl, (3-cyano-pyridin~2-yl)methyl, (4-methyl-pyrimidin-2-yl)methyl, or (4,6-dimethyl-pyrimidin-2-yl)methyl and R2 denotes 3-(R)-amino-piperidin-1-yl, (2-amino-2-methyl-propyl)-methylamino or(2-(S)-amino-propyl)-methylamino,

for preparing a medicament combination with an active substance selected from among the other antidiabetics; active substances that lower the blood sugar level; active substances that lower the lipid level in the blood; active substances that raise the HDL level in the blood; active substances that lower blood pressure; and active substances that are indicated in the treatment of atherosclerosis or obesity.

…

*14. **Isolation or storage medium** for islets of Langerhans or beta cells, characterised in that the medium contains 1nmol/1 to 1 µmol/1 of a DPP IV inhibitor for enhancing the vitality and secretion capacity of the cells.*

...

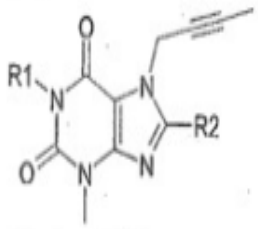
*15. **Method** of enhancing the vitality and secretion capacity of iselts of Langerhans or beta cells, characterised in that during the isolation and transplantation phase of the islets of Langerhans or beta cells a DPP IV inhibitor is added to the isolation and storage medium in a concentration of between 1 nmol/1 and 1nmol/l and 1 µmol/l."*

18. Thereafter, Amendment No.1 filed in response to the FER dated 24th March, 2014, reduced the Claims to the following:

"*We Claim*

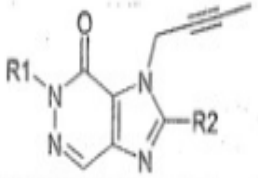
1. Isolation or storage medium for islets of Langerhans or beta cells, characterised in that the medium contains 1nmol/1 to 1 µmol/1 of a DPP iv inhibitor for enhancing the vitality and secretion capacity of the cells.

2. Medium as claimed in claim 1, wherein the structure of the DPP IV inhibitor is described by the formula(1)



(I)

or the formula (II)



(II)

R1 denotes ([1 ,5]naphthyridin-2-yl)methyl, (quinazolin-2-yl)methyl, (quinoxalin-6-yl)methyl, (4-methyhquinazolin-2-yl)methyl, 2-cyano-benzyl, (3-cyano- quinolin-2-yl)methyl, (3-cyano-pyridin-2-yl)methyl, (4-methyl-pyrimidin-2-yl)methyl, or (4,6-dimethyl-pyrimidin-2-yl)methyl and

3. Method of enhancing the vitality and secretion capacity of iselts of Langerhans or beta cells, wherein during the isolation and transplantation phase of the islets of Langerhans or beta cells a DPP iv inhibitor is added to the isolation and storage medium in a concentration of between 1 nmol/l and 1nmol/l."

19. Two more Amendments were carried out after this. Claim No.1 of Amendment No.2 reads as under:

> *"A medicament combination of a DPP IV inhibitor which is 1- [(4-Methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-l-yl)-8-(3-(R)aminopiperidin-l-yl)-xanthine, or one of the*

therapeutically active salts thereof, in a dosage of 2.5 mg to 10 mg for oral administration, with metformin."

20. Claim No.12 of Amendment No.3 reads as under:

"A medicament combination of a DPP IV inhibitor which is 1 -[(4-Methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-I-yl)-8-(3-(R)amninopiperidin-1-yl)-xanthine, or one of the therapeutically active salts 1hereof, with telmisartan."

21. Thus, Amendment Nos. 2 and 3 were for different combinations of DPP-IV inhibitors with Metformin and Telmisartan respectively in medicament i.e., product form.

22. A perusal of the original patent application along with its Complete Specification and of the Amendments filed thereafter, reveals the following facts:

(i) The title of the parent application itself is '***Use*** *of DPP IV inhibitors*'.

(ii) All the Claims in the parent application i.e., Claims 1 to 18 are either use claims or method claims. There is not even a single product claim in the entire set of claims.

(iii) In Amendment No.1, the Applicant sought to restrict Claims 1 to 18 including Claims 15 & 15A to only three claims i.e., Claims 14, 15 & 15A. All the other method or use claims were given up by the Applicant.

(iv) In Amendment Nos. 2&3 however, the Applicant sought to add new Claims, which were product Claims 1 to 11 and product Claims 1 to 15. Amendment No.1 discussed a medicament

combination of a DPP IV inhibitor with metformin whereas Amendment No.2 discussed a medicament combination of a DPP IV inhibitor with telmisartan. Clearly, these product Claims were not contained in the parent application at all, as the Markush formula depicted in the parent application itself was not a *'product claim'*, but a *'use claim'*.

Divisional Application

23. After the Amendments, a divisional application was filed. The Claims in the divisional application are extracted below:

> *"1. A medicament of a DPP IV inhibitor which is 1-[(4-methyl-quinazolin-2-yl)methyl]-3- methyl-7-(2-butyn-1-yl)-8-(3-(R)-aminopiperidin-1-yl)-xanthine, or one of the therapeutically active salts thereof, in a dosage of 2.5 mg to 10 mg for oral administration, optionally in combination with another antidiabetic or a blood pressure-lowering active substance.*
> *2. The medicament combination according to claim 1 of a DPP IV inhibitor which is 1-[(4-Methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine,*
> *in a dosage of 2.5 mg or 5 mg for oral administration, with metformin, either in a free combination or in a fixed combination.*
> *3. The medicament combination according to claim 2 of a DPP IV inhibitor which is 1-[(4-Methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine,*
> *in a dosage of 2.5 mg or 5 mg for oral administration, with metformin, either in a fixed combination, which is a tablet or capsule.*
> *4. The medicament combination according to claim 3 of a DPP IV inhibitor which is 1-[(4-Methyl-*

quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine,
in a dosage of 2.5 mg for oral administration, with metformin, in a fixed combination, which is a tablet.

5. The medicament combination according to claim 3 of a DPP IV inhibitor which is 1-[(4-Methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine,
in a dosage of 5 mg for oral administration, with metformin, in a combination, which is a tablet.

6. The medicament combination according to claim 2 of a DPP IV inhibitor which is 1-[(4-Methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine,
in a dosage of 5 mg for oral administration, with metformin, in a free combination.

7. The medicament combination according to any one of the claims 1 to 6, wherein the dose of metformin is 500-2850 mg.

8. The medicament combination according to any one of the claims 1 to 6, wherein the dose of metformin is 500 mg, 850 mg or 1000 mg.

9. The medicament combination according to any one of the claims 1 to 6, wherein the dose of metformin is 300 mg to 1000 mg once or twice a day, or delayed-released metformin in a dose of 500 mg to 1000 mg once or twice a day or 500 mg to 2000 mg once a day.

10. The medicament combination according to any one of the claims 1 to 6, wherein the dose of metformin is 500 mg to 850 mg once or 1000 mg metformin as a single dose with a totally daily dose of metformin of 500-2850 mg, or 500 mg, 1000 mg, 1500 mg or 2000 mg metformin in a delayed release form.

11. The medicament combination according to any one of the claims 1 to 10, wherein the oral daily dose of the DPP IV inhibitor is 5 mg.

12. A method of preparing a combination of a DPP IV inhibitor which is 1-[(4-methylquinazolin- 2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-aminopiperidin-1-yl)-xanthine, or one of the

therapeutically active salts thereof, with metformin, said method is characterized by combining the DPP IV inhibitor in a dosage of 2.5 mg or 5 mg with metformin in a dosage of 500 mg, 850 mg or 1000 mg.

13. The method according to claim 12, wherein the daily oral dose of metformin is 500-2850 mg and the daily oral dose of the DPP IV inhibitor is 5 mg.

14. The medicament combination according to claim 1 of a DPP IV inhibitor which is 1-[(4- methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-aminopiperidin-1-yl)-xanthine, in a dosage of 2.5 mg to 10 mg for oral administration, with telmisartan, either in a free combination or in a fixed combination.

15. The medicament combination according to claim 14, wherein the dosage of the DPP IV inhibitor is 2.5 mg or 5 mg for oral administration.

16. The medicament combination according to 14 or 15, wherein the dosage of telmisartan is 20 mg to 320 mg or 40 mg to 160 mg per day.

17. The medicament combination according to claim 14, 15 or 16, wherein the oral daily dose of the DPP IV inhibitor is 5 mg.

18. A medicament of a DPP IV inhibitor which is 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-aminopiperidin-1-yl)-anthine, or one of the therapeutically active salts thereof, wherein the medicament is for oral administration and contains a dosage of 2.5 mg to 10 mg (such as e.g.2.5 mg, 5 mg or 10 mg) of 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-aminopiperidin-1-yl)-xanthine.

19. A method of preparing a medicament of a DPP IV inhibitor which is 1-[(4-methylquinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-aminopiperidin-1-yl)-xanthine, wherein the medicament is for oral administration, said method is characterized in that the DPP IV inhibitor in a dosage of 2.5 mg to 10 mg (such as e.g.2.5 mg, 5 mg or 10

mg) is formulated together with one or more inert carriers and/or diluents.

20. The medicament according to claim 18 or the method according to claim 19, wherein a medicament is formed which is a galenic preparation selected from a tablet or coated tablet.

21. The medicament or method according to any one of claims 18 to 20, wherein the DPP IV inhibitor is formulated together with mannitol, pregelatinised starch, maize starch, copovidone and magnesium stearate.

22. The medicament or method according to any one of claims 18 to 21, wherein the medicament is in the form or a film-coated tablet, wherein 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, mannitol, pregelatinized starch maize starch, copovidone and magnesium stearate are present in the tablet core coated with a film-coating of hydroxypropylmethyl-cellulose, polyethyleneglycol, talc, titanium dioxide and iron oxide.

23. The medicament or method according to any one of claims 18 to 22, wherein 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, mannitol, pregelatinized starch, maize starch, copovidone are not wet granulated.

24. The medicament or method according to any one of claims 18 to 23, wherein the dosage of the DPP IV inhibitor is 2.5 mg or 5 mg.

25. The medicament or method according to any one of claims 18 to 24, wherein the oral daily dose of the DPP IV inhibitor is 5 mg."

24. Thus, the divisional application consists of 25 claims. Claims 1-11, 14-18, 20-25 are all product claims for medicaments which are DPP IV Inhibitors in various combinations, modes of administration, dosage forms, etc. Claims 12, 13 and 19 are method claims for some combinations and dosage forms. Notably, Claims 1-17 of the divisional application were

reflected in some form in Amendment Nos. 2&3. Claims 18-25 appear to be completely new claims in the divisional application.

25. This Court also notes that a hearing was held by the Controller in respect of the parent application and Amendment Nos. 2&3 in August, 2017. Pursuant to the said hearing, the Controller appears to have expressed his opinion that Amendment Nos. 2&3 would not be allowable. After the hearing in August 2017, the Applicant filed the Divisional Application on 4th September 2017. One day thereafter, i.e., 5th September 2017, written submissions were filed in respect of the Amendments and the parent application. The Controller passed the written order in January 2018, refusing the amendments as also the parent application. The timing of filing the divisional application is thus very interesting.

26. In so far as the divisional application itself is concerned, this case raises an important issue as to whether divisional applications can be filed for claims, when such claims were not part of the claims in the parent application. In order to answer this question, a conjoint reading of Sections 10, 15 & 16 of the Act would be needed.

27. The relevant portions of Sections 10, 15 & 16 of the Act are extracted herein below:

> "***Section 10. Contents of specifications***
>
> *(1) Every specification, whether provisional or complete, shall describe the invention and shall begin with a title sufficiently indicating the subject-matter to which the invention relates.*
>
> …
>
> *(4) Every complete specification shall--*
>
> *(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;*

(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and
*(c) end with a claim or claims **defining the scope of the invention** for which protection is claimed.*

…

[(5) The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification.]

…

(7) Subject to the foregoing provisions of this section, a complete specification filed after a provisional specification may include claims in respect of developments of, or additions to, the invention which was described in the provisional specification, being developments or additions in respect of which the applicant would be entitled under the provisions of section 6 to make a separate application for a patent.

XXX

Section 15 Power of Controller to refuse or require amended applications, etc., in certain cases.

***15. Power of Controller to refuse or require amended applications, etc., in certain cases**.--Where the Controller is satisfied that the application or any specification or any other document filed in pursuance thereof does not comply with the requirements of this Act or of any rules made thereunder, the Controller may refuse the application or may require the application, specification or the other documents, as the case may be, to be amended to his satisfaction before he proceeds with the application and refuse the application on failure to do so.*

Section 16 Power of Controller to make orders respecting division of application

(1) A person who has made an application for a patent under this Act may, at any time before the grant of

the patent, if he so desires, or with a view to remedy the objection raised by the Controller on the ground ***that the claims of the complete specification relate to more than one invention****, file a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application.*

(2) The further application under sub-section (1) shall be accompanied by a complete specification, but such complete specification shall not include any matter not in substance disclosed in the complete specification filed in pursuance of the first mentioned application.

(3) The Controller may require such amendment of the complete specification filed in pursuance of either the original or the further application as may be necessary to ensure that neither of the said complete specifications includes ***a claim*** *for any matter claimed in the other.*

…"

28. From the above provisions, it is clear that a divisional application under Section 16 of the Act, has to be an application which arises from a parent application disclosing a "plurality of inventions". In Section 16(1), the phrase "*the claims of the complete specification relate to more than one invention*" makes this position clear. Section 16(3) also makes it clear that there cannot be duplication of the claims in the two specifications i.e., parent specification and the divisional application. This leads us to the question as to how to determine "plurality of inventions". For this, guidance can be drawn from Section 10 of the Act which elaborates on the meaning of complete specification and scope of claims.

29. Importantly, Section 10 of the Act clearly requires the applicant to define the scope of the invention. It provides that every complete

specification has to:

- Begin with a title indicating the subject matter of the invention;
- Fully and particularly describe the invention;
- Fully and particularly describe the operation or use of the invention;
- Fully and particularly describe the manner which the invention has to be to performed;
- Disclose the best method of performing the invention, which is known to the applicant and for which the applicant is entitled to claim protection;
- End with a claim or claims – the claims define the scope of the invention for which the protection is sought; and
- Have an abstract of the invention.

30. A perusal of these conditions as stipulated under Section 10 shows that the title indicates the subject matter of the invention. The content of the specification describes the invention. The complete specification also describes the procedures, processes, methods, including the best methods. But what is crucial to note, is the fact that the invention itself is defined in the claims. While such claims do have to be based on the disclosure in the specification, however even if a person does not read the complete specification and wishes to identify the invention, the place to look for it is in the 'Claims'. The Invention thus resides in the Claims. Accordingly, "unity of the invention"/ "plurality of inventions" and whether they form a "single inventive concept" has to be gleaned from a reading of the claims. This position has been examined and held so by the IPAB as well in ***ESCO***

Corporation v. Controller of Patents & Designs [OA/66/2020/PT/DEL, decided on 27th October, 2020], where the IPAB observed:

> *"10.* ***Therefore, looking at the provisions of law and the settled practices, we reach the following conclusions that a patent application can only be divided, if it claims more than 'one invention'. Now the question therefore is how "one invention" is defined.*** *We look at the provisions of "unity of invention" as provided in section 10(5) of the Patents Act, 1970. It says 'The claim or claims of a complete specification shall relate to a* ***single invention, or to a group of inventions linked so as to form a single inventive concept****". Means if any specification claims* ***either a single invention or a group of invention linked so as to form a single inventive concept****, the requirement of "unity of invention" is satisfied. Hence, if there is no objection on the ground of 'plurality of distinct inventions' means the claims of the complete specification, contains either* ***a single invention or a group of inventions linked so as to form a single inventive concept*** *and in such a scenario, no divisional application is allowable."*

31. Using this understanding of how an invention is ascertained in a patent application, it is clear that under Section 16 of the Act, the "plurality of inventions" should clearly exist in the claims of the original parent application and within the scope of the specification of the parent application. Therefore, under Section 16, the question of whether the claims of the complete specification relate to more than invention i.e., a "plurality of inventions" has to be seen from the claims of the parent application. Obviously, the claims in turn, have to be based on the disclosure in the specification. However, if the invention is not contained in the claims of the parent application, the divisional application cannot be permitted to be filed

solely on the basis of disclosure made in the specification, in respect of alleged inventions. If applicants are permitted to file such divisional applications on the basis of disclosure in the complete specification, without such inventions being claimed in parent applications, it would defeat the fundamental rule of patent law i.e., *'what is not claim is disclaimed'*.[1] Similarly, Section 59 also makes it clear that amendments beyond the scope of the specification and claims would not be permissible. This is the settled legal position, as also held by this Court in ***Nippon A&L Inc. v. The Controller of Patents [C.A. (COMM.IMPD-PAT) 11/2022, decided on 5th July, 2022]***. Thus, the divisional application would be maintainable only when the claims of the parent application disclose "plurality of inventions".

32. This position of law is also borne out by various decisions of the IPAB. For instance, most recently in ***ESCO (supra)***, the IPAB held as under:

> *"10.* ***Therefore, looking at the provisions of law and the settled practices, we reach the following conclusions that a patent application can only be divided, if it claims more than 'one invention'. Now the question therefore is how "one invention" is defined.*** *We look at the provisions of "unity of invention" as provided in section 10(5) of the Patents Act, 1970. It says 'The claim or claims of a complete specification shall relate to a* ***single invention, or to a group of inventions linked so as to form a single inventive concept****". Means if any specification claims* ***either a single invention or a group of invention linked so as to form a single inventive concept****, the requirement of "unity of invention" is satisfied. Hence, if there is no objection on the ground of 'plurality of*

[1] Nippon A&L Inc. v. The Controller of Patents [C.A. (COMM.IMPD-PAT) 11/2022, decided on 5th July, 2022]; Manual of Patent Office Practice and Procedure, published by the Office of the Controller General of Patents, Designs and Trademarks, dated 26th November, 2019.

distinct inventions' means the claims of the complete specification, contains either ***a single invention or a group of inventions linked so as to form a single inventive concept*** *and in such a scenario, no divisional application is allowable.*

…

13. The issue of divisional applications has drawn much attention in recent past and we have noted different practices adopted by the applicants or by the Patent Office. We, therefore, opine that in the best interest of justice and in order to bring uniformity of practices, the following guiding principle may help to address the issue. Considering the above legal provisions of Indian Patent law, the Manual Of Patent Office Practice and Procedure, the PCT to which India in a member since 1998 and the previous decisions, we are of the view that the following points need be adhered to while dealing with divisional applications:

14. Formal Grounds:

14.1 ***Filing of divisional application***

- ***Either by the applicant (suo-moto), if he so desires or***
- *To remedy the objection raised by the Controller on the ground of plurality of invention.*
- ***In either case the existence of plurality of invention in the parent application is the sine qua non for a divisional application.***

14.2 The claims of divisional application shall have their route in the first mentioned (parent) application. ***This is true even for divisional to divisional application as well.*** *The routes of subsequent divisional application also should be from the first mentioned application. The divisional application shall not be filed with the same set of claims as the first mentioned application.*

14.3 The applications need be divided only on the ground of 'plurality of invention' as envisaged under section 16. ***If any claim is held to be non-patentable due to any other provisions of the law such as the***

requirements section 3 or otherwise, it should not be proper for filing a divisional application for such claims.

14.4 For division of an application, the primary requirement is that the application shall exist. Meaning thereby that no divisional application can be filed, if the application is either "deemed to be abandoned" or 'withdrawn" or "refused". However, the divisional application once filed, no such subsequent action will have any bearing on that divisional application, which shall continue as substantive application.

…

14.7 The complete specification of the divisional application shall not include any matter not in substance disclosed in the complete specification of first mentioned application. ***The teaching of sub section (2) of section 16 doesn't refer to the matter disclosed but not claimed****. This relates to the fact that since both the applications are given the same date of filing, the latter shall not include any further subject matter which was not disclosed in the first mentioned application.* ***Therefore, the contention that some additional claim(s) can also be allowed, which never formed part of the originally filed claims, is negated as the provisions of law need to be read in totality****. A plain reading of sub -section (1) of section 16 reveals that the very ground to accept divisional application is "on the ground that the claims of the complete specification relate to more than one inventions. Sections 10(5) further qualifies "more than one invention" to only such invention or group thereof which cannot be linked to make a single inventive concept.*

Substantive Grounds:

14.8 At the stage of examination, care should be exercised that merely by the presence of different embodiments in the specification, which are claimed as independent set of claims, it does not necessarily attract the provisions of lack of Unity of invention'. If the unity of invention is not ascertained, the

> *amendement of the claims can overcome the "scope" or "definitiveness" requirements, and this option could well be excercised before hand."*

33. This position also finds favour in the IPAB's decision of ***LG Electronics, Inc. v. Controller of Patents & Designs [OA/6/2010/PT/KOL, decided on 10th August, 2011]***. The said decision reads as under:

> *"The concept of divisional application in the patent law basically addresses the issues of allowability of protection of multiple inventions disclosed in one patent application, where these multiple inventions do not constitute a single inventive concept. The protection of multiple inventions through divisional application is available in the Patents Act 1970 under the provisions of section 16 and section 10(5) reproduced below.*
>
> …
>
> *We agree with the applicants arguments that the applicant can file an application as divisional application of his own before the grant of patent. However Respondent-2 is mandated by the law to ascertain that the divisional application so filed is on account of disclosure of plurality of distinct invention in the parent application. Section 16 pertains to power of the Respondent to make order respecting division of application.* ***Right to file divisional application indeed rest with the applicant but the power to ascertain its allowability is vested with the Respondent.*** *The first essential requirement of this provision is the fact of existence of plurality of invention in the parent application."*

34. Even in ***Milliken (supra)*** which has been relied upon by the Applicant, the parent application had a plurality of inventions in its claims

which was then moved to the first divisional application and then to the second divisional application.

35. In view of the above discussed settled position in law, this Court is clearly of the opinion that a divisional application in the present case cannot be filed since there was no "plurality of inventions" in the parent application. In the present case, the original 'DPP IV inhibitor' arising out of a Markush formula, in various permutations and combinations describing its use and method for treatment, which is only mentioned in the examples in the specification, cannot be permitted to be claimed as separate product Claims in a divisional application, as there were no product Claims in the parent application. Clearly, the Claims in the parent application only related to method or use claims whereas, the Claims in the divisional application concern "products" i.e., medicaments or their combinations. Once the product Claims were not sought in the original application and the said products were clearly disclosed in the content of the complete specification, the products ought to be treated as having been disclaimed. Thus, the parent application cannot be interpreted to have included a "plurality of inventions", i.e., completely new product Claims, patentable by way of a divisional application.

36. In view of the above findings, this appeal is held to be completely devoid of any merits. Considering that such long-drawn proceedings emanated from one parent application, resulting in two separate applications, three Amendments and the time that has been consumed between 2008 to 2017, and the timing of the divisional application, this Court deems it fit to reject the appeal along with payment of some costs by the Applicant. Hence, the appeal is rejected with costs of Rs.50,000/- to be paid by the Applicant

within four weeks. Out of this amount, Rs.25,000/- shall be paid to the ld. Counsel for the Respondent. The remaining Rs.25,000/- shall be paid to the DHCBA Pandemic Relief Fund [A/c No.15530110152195, IFSC Code-UCBA0001553, UCO Bank, Delhi High Court]. The said amount shall be utilised only for the purposes of distribution to lawyers and their families who have deceased during the pandemic. Hony. Secretary, Delhi High Court Bar Association to confirm receipt of the said amount, within four weeks.

37. The present appeal is accordingly dismissed. All pending applications are disposed of.

38. The digitally signed copy of this order, duly uploaded on the official website of the Delhi High Court, www.delhihighcourt.nic.in, shall be treated as the certified copy of the order for the purpose of ensuring compliance. No physical copy of orders shall be insisted by any authority/entity or litigant.

PRATHIBA M. SINGH
JUDGE

JULY 12, 2022/*dk/ms*
(corrected & released on 20th July, 2022)