COMPETITION COMMISSION OF INDIA

Case No. 25 of 2022

In re:

Macleods Pharmaceuticals Limited **Informant**

Atlanta Arcade, Church Road

Near Leela Hotel, Andheri - Kurla Road

Andheri (East), Mumbai – 400059

And

Boehringer Ingelheim Pharma GmbH & Co. KG D **Opposite Party No. 1**

55216, Ingelheim am Rhein

Germany

Boehringer Ingelheim India Private Limited **Opposite Party No. 2**

202, 2F, Godrej 2, Pirojsha Nagar, Eastern Express Highway, Vikhroli East, Mumbai City, Maharashtra – 400079

CORAM:

Ms. Ravneet Kaur
Chairperson

Ms. Sangeeta Verma
Member

Mr. Bhagwant Singh Bishnoi
Member

Order under Section 26(2) of the Competition Act, 2002

1. The present Information has been filed by Macleods Pharmaceuticals Limited "**Informant**") under Section 19(1)(a) of the Competition Act, 2002 ("**Act**") alleging contravention of Section 4(1) read with 4(2)(c) of the Act by Boehringer Ingelheim Pharma GmbH & Co. KG ("**OP-1**") and Boehringer Ingelheim India Private Limited ("**OP-2**"), (hereinafter, collectively referred to as the "**Opposite Parties**").

2. The Informant is stated to be a pharmaceutical company incorporated under the erstwhile Companies Act, 1956, and is engaged in development and manufacturing of Active Pharmaceutical Ingredients (APIs) and finished dosage pharmaceutical formulations.

3. OP-1 is a company incorporated under the laws of Germany and is stated to be among the world's largest pharmaceutical companies. OP-2 is a company incorporated under Companies Act, 1956 and is a subsidiary of OP-1. OP-2 has the permission of the Drugs Controller General of India ("**DGCI**") to import and market, Linagliptin Tablet and FDC of Linagliptin + Metformin Hydrochloride tablets which is the formulation of 'Linagliptin'.

4. OP-1 holds two patents bearing nos. IN 227719 under the title "*Xanthine Compounds*" which was valid for a period of 20 years with effect from 21.02.2002 till 21.02.2022 ("**First Patent"**) and IN 243301 under the title "*8-3 Aminopiperidin-I-yl-xanthine compounds*" which is valid till 18.08.2023 ("**Second Patent**"). Both patents were granted to the Opposite Parties on the basis of two international applications dated 21.02.2002 and 18.08.2003. The compound 'Linagliptin' which is used in drugs for treatment of Type 2 diabetes has been claimed in both the patents.

5. It has been stated by the Informant that First Patent was claimed with Markush Structure, which allows patents of novel structure that can have many possible substituents. As per the Informant, Markush claim allows a patent drafter to condense a multitude of alternate dependent claims into one single claim.

6. As per the Informant, both the patents, one of which have now expired, cover 'Linagliptin' compound and that the Opposite Parties are using their Second Patent to prohibit their competitors, including the Informant from using 'Linagliptin' in their drugs, which by their own admission was covered in its now expired patent, First Patent.

7. It has been alleged that the Opposite Parties, by filing multiple patents are artificially extending the period of protection beyond 20 years which is causing appreciable adverse effect on competition in the market, resulting in higher prices of drugs and denial of market access as no other competitor can enter the market.

8. With respect to the compound 'Linagliptin', it has been submitted that it is used for patients having Type 2 diabetes with renal problems. It is further submitted that one of the treatments used to cure Type 2 diabetes involve inhibiting the enzyme dipeptidyl peptidase-4 (DPP-4). DPP-4 Inhibitors block the action of DPP-4, and hence regulate production of insulin in human body. One of such DPP-4 inhibitors, as per the Informant is 'Linagliptin'. Unlike other DPP-4 inhibitors, 'Linagliptin' can be used without dose adjustment in patients with renal or hepatic impairment. Thus, doctors prescribe 'Linagliptin' in special cases where the patients have some kidney related complications.

9. It has been alleged that the descriptions of First Patent and Second Patent are not merely substantially similar, but are in fact identical in several parts. As per the Informant, the sections in First Patent and in Second Patent relating to field of the invention, background of the invention, including reference to relevant prior art, description of the invention are identical. The Informant has thus alleged that once First Patent expired, the Informant was free to use and commercially exploit 'Linagliptin'. However, the Opposite Parties filed multiple frivolous suits for alleged infringement of Linagliptin (Second Patent), denying market access to the Informant.

10. It has been alleged that Opposite Parties, in declaration to Form 27 of Patents Act, 1970 have admitted that First Patent covers 'Linagliptin' and under Second Patent, it is

commercially sold. It has been stated that Opposite Parties have filed a suit for permanent injunction being CS (COMM) No. 240 of 2019, before the Hon'ble Delhi High Court against Vee Excel Drugs and Pharmaceuticals Ltd. alleging infringement of First Patent and Second Patent, admitting that 'Linagliptin' was covered in both the patents. It has been stated that a similar case has been filed in Canada against Sandoz Canada Inc..

11. In addition to above, Opposite Parties also sent cease and desist notice dated 01.11.2021 to the Informant stating that both patents, First Patent and Second Patent cover 'Linagliptin', and that the Informant should cease and desist from launching, making, using, selling, offering to sell 'Linagliptin' in any form whatsoever.

12. It has been alleged that the dispute started when after expiry of First Patent on 21.02.2022, the Informant and other competitors of the Opposite Parties, started using 'Linagliptin' which by operation of law became public and began manufacturing 'Linagliptin' based drugs. The Informant also started manufacturing 'Linagliptin' 5 mg tablets under the brand names "Linamac" and "Linaone". However, the Opposite Parties restricted its competitors from using the knowledge of its First Patent on the ground that it also infringes Second Patent. This has been alleged to be clear abuse of process.

13. Thereafter, the Opposite Parties filed a commercial suit bearing no. COMS No. 03 of 2022 against the Informant before the Hon'ble Himachal Pradesh High Court seeking permanent injunction restraining the Informant from using the compound 'Linagliptin'. As per the Informant, the Opposite Parties did not emphasise before the said court that 'Linagliptin' was covered in First Patent but has rather claimed that First Patent covered '*Xanthine compounds*' for Markush formula being the genus patent while Second Patent is the species patent.

14. In addition to above, it has been alleged that Opposite Parties also sent communication to third parties, like doctors, asking them not to deal with competitors of Opposite Parties including the Informant selling 'Linagliptin'. One such WhatsApp communication dated 25.02.2022 has been referred to by the Informant in the Information.

15. It has been alleged that the Second Patent granted to the Opposite Parties was secured on the basis of an active suppression and misrepresentation of facts before the Controller of Patents, who consequently granted protection to the Opposite Parties for the same invention and subject matter covered and claimed in the earlier patent i.e. First Patent which is not permissible under the law. Therefore, the Informant filed a Revocation Petition before the Hon'ble Delhi High Court in terms of section 64 (1) of the Patents Act, 1970 seeking revocation of patent Second Patent on the grounds, *inter alia*, that the First Patent covered the same compound, viz., 'Linagliptin'. The said Revocation Petition is pending adjudication before the Hon'ble Delhi High Court.

16. In relation to delineation of the relevant market, it has been stated that in the instant case, the pharmaceutical drugs in question are based on 'Linagliptin', which is specifically used for treatment of patients with Type 2 diabetes having renal (kidney related) complications. From the perspective of doctors, there are no substitutes for 'Linagliptin'. Further, the drugs in question are imported or manufactured for the purpose of sale in India. Hence, the relevant geographic market would be India. Accordingly, relevant market proposed by the Informant is "*market for biological drugs based on Linagliptin for treatment of Type 2 diabetes in India".* According to the Informant, Opposite Parties hold a dominant position in the delineated relevant market, as the Opposite Parties are the sole manufacturer and seller of 'Linagliptin' in India and have a 100% market share.

17. With respect to abuse of dominant position by the Opposite Parties, the Informant has stated that Opposite Parties by obtaining a Second Patent for the same molecule which was covered in the First Patent, which now stands expired, has attempted to evergreen its patent. By doing so, the Opposite Parties are keeping the competitors away for another 1.5 years, denying market access, limiting production of goods in the market, limiting technical and scientific development relating to drugs based on 'Linagliptin' causing prejudice to end consumers (patients).

18. The Informant has stated that the Opposite Parties have indulged in contravention of Section 4 of the Act, by engaging in frivolous and vexatious litigation to prohibit competitors from using 'Linagliptin'. In this regard, reliance is placed on Commission's previous Case No. 105/2013 (*In Re: M/s Bull Machines Pvt. Ltd.).* Further, it has been alleged that Opposite Parties have indulged in contravention by giving notices to third parties to not engage with the Informant.

19. On the basis of the averments made above, the Informant has, *inter alia*, prayed to the Commission to initiate an investigation under Section 26(1) against the Opposite Parties for contravening the provisions of the Act. The Informant has further prayed to prohibit the Opposite Parties from approaching third parties against the products of the Informant along with a prayer to pass any other direction as may be deemed appropriate under the Act.

20. The Commission had considered the Information and material available on record in its ordinary meeting held on 20.07.2022 and decided to seek response/reply of the Opposite Parties on the Information filed, if any, within four weeks of receipt of the said order, with an advance copy to the Informant. The Commission also directed the Informant to file its further response, if any, within two weeks thereafter, with an advance copy to the Opposite Parties. Accordingly, the Opposite Parties submitted their response dated 31.10.2022, in the confidential as well as non-confidential versions, after seeking extension of time. The Informant, however, did not file any response/rejoinder to the response submitted by the Opposite Parties.

21. The Opposite Parties, in their response have stated that they have lawfully exercised their statutory right to protect a legitimately granted and active patent under the Patents Act, 1970. Further, the information is premature and outside the Commission's jurisdiction. It has been stated that the Commission's jurisdiction is secondary to that of the Hon'ble Delhi High Court, where a revocation petition filed by Informant is pending. The legality of the actions of Opposite Parties hinges upon the validity of the Second Patent and the alleged conduct does not seem to be unlawful. The Informant would need to demonstrate how a

legitimate patent dispute could constitute an abuse of dominance. The Opposite Parties have engaged in co-marketing agreements with certain companies for their 'Linagliptin' based drug and thus have not foreclosed the market. With respect to the allegation pertaining to evergreening concerning the Second Patent, it has been submitted that OP-1 filed an international patent application for this patent in 2003 before it was approved in 2010 and the Patents Act, 1970 was amended to curb evergreening. It has been submitted that the Controller of Patents would have considered these amendments when granting the Second Patent. Therefore, the validity of the Second Patent is acknowledged in several countries, including India and Canada. It has been further submitted that an *ad interim* injunction was granted *vide* order dated 25.02.2022 against the Informant and made absolute *vide* order dated 21.04.2022 by the Hon'ble Himachal Pradesh High Court in CS (COMM) No. 3 of 2022 which further strengthens the fact the Second Patent is valid. Neither the Informant nor any third party filed any pre grant or post grant opposition against the Second Patent which establishes the novelty, inventive step, quality and strength of the Second Patent. It has also been submitted that the revocation petition, as discussed above, was filed by the Informant against the Second Patent, in close proximity to undermine the suit for permanent prohibitory injunction filed by the Opposite Parties.

22. The Opposite Parties have submitted that the Informant has incorrectly delineated the relevant market and suggested that main relevant market defined by the Informant should be at an Anatomical Therapeutic Chemical (ATC)-3 level *i.e. "drugs (at an ATC-3 level) for treatment of Type 2 diabetes in India" or* alternatively, be delineated as *"drugs (at an ATC 4 level) based on molecules /compounds/ APIs within the 'gliptins' chemical subgroup to treat Type 2 diabetes with renal complications in India"*. The Opposite Parties have submitted that in terms of conditions provided under section 19 (4) of the Act, OP-2 is not dominant in any of the defined relevant markets and therefore does not have the ability to act independent of competitive forces, and faces fierce competition by well-established, deep pocketed competitors. The Opposite Parties have further contended that they operate in a competitive market with numerous substitutes from major players and that Informant itself offers 'Tenlimac,' a Type-2 diabetes medication, as a direct substitute for 'Linagliptin,' requiring no dosage adjustment even in renal complications. It has been

submitted that the period of the alleged contravention is extremely short for Opposite Parties to perpetrate any appreciable adverse effect on competition. Further, OP-2 does not have any ability to increase pricing (regardless and without prejudice to its dominant position) as all pharmaceutical companies are regulated by the National Pharmaceutical Pricing Authority which is a government regulatory agency that controls the prices of pharmaceutical drugs in India. Given the validity of the Second Patent, Opposite Parties have only acted in a lawful manner, exercising such options available to them and as such its conduct is not vexatious, frivolous or unlawful. Thus as per the Opposite Parties the Information is incorrect on facts, untenable in law and contains a set of false allegations and thus liable to be rejected.

23. The Commission has perused the Information, response to the Information filed by the Opposite Parties and other material available on record. The primary grievance of Informant is that the Opposite Parties, by engaging in vexatious and frivolous patent litigation against the Informant and other competing pharmaceutical companies and by giving notices to third parties such as medical practitioners, are prohibiting the Informant and its competitors from using 'Linagliptin' in its drugs, for the treatment of Type 2 diabetes. This conduct has been alleged to be abuse of dominant position by Opposite Parties and in contravention of provisions of Section 4 of the Act.

24. The issue for *prima-facie* determination before the Commission is whether the alleged conduct of the Opposite Parties of initiating frivolous and vexatious legal proceedings against the Informant and subsequent communications to the doctors asking them not to deal with its competitors including the Informant, selling 'Linagliptin', is in contravention of the provisions of Section 4 of the Act.

25. The Commission, based on its previous orders, observes that a litigation from a competition perspective may be termed as frivolous and vexatious when it is initiated by a dominant undertaking to cause anti-competitive harm, *via*, the inappropriate use of adjudicatory/government processes or legal rights. Usually, the objective behind such

litigation is to either subdue a competitor by increasing operational costs or delay the entry of a competitor in the market.

26. The Commission notes that, to determine whether a litigation or legal recourse is an abusive conduct of a dominant player, *firstly*, it needs to be established that a case filed against an enterprise on an objective view is baseless and appears to be an instrument to harass the enterprise. *Secondly*, what needs to be examined is whether the legal action appears to be conceived with an anti-competitive intent/plan to eliminate/thwart competition in the market. The lawsuit must be objectively baseless that no reasonable litigant could realistically expect success on the merits and be filed and prosecuted, not with a view to protect a legitimate right but to prevent a competitor from effectively competing or thwarting a potential entrant into the market.

27. In order to understand whether the litigation filed by the Opposite Parties is baseless and an abusive under the provisions of the Act, the Commission has taken note of litigations/disputes between Opposite Parties, Informant and other competitors. The Opposite Parties instituted a commercial suit bearing CS (COMM) No. 3 of 2022 before the Hon'ble Himachal Pradesh High Court against the Informant. It is stated that after expiry of first patent (IN 719) on 21.02.2022, the Informant started manufacturing drugs based on "Linagliptin" under the brand names Linamac and Linaone. Upon obtaining knowledge of the pre- marketing and stock piling by the Informant in relation to 'Linagliptin', the Opposite Parties filed a suit for permanent injunction for restraining the Informant from infringing the patents owned by Opposite Parties under the Patents Act, 1970. It is noted that the Hon'ble Himachal Pradesh High Court passed an interim order dated 25.02.2022 and directed the Informant to not manufacture and sell products based on 'Linagliptin'. The Commission notes that *ad-interim* protection granted to the Opposite Parties was made absolute during the pendency of the civil suit *vide* order dated 21.04.2022. This case is pending adjudication before the Hon'ble Himachal Pradesh High Court.

28. As per the information available in public domain, the Opposite Parties had also obtained *ad-interim* injunctions against four other pharmaceutical companies that launched generic versions of Opposite Party's patent-protected drug 'Linagliptin', which is marketed under the brand name 'Trajenta'. In relation to various suits filed by the Opposite Parties against the competitors such as Vee Excel Drugs and Pharmaceuticals Pvt. Ltd., Alkem laboratories Ltd., Micro labs Ltd., Natco Pharma Ltd, the Hon'ble High Court of Delhi *vide* order dated 29.03.2023 has vacated the interim injunction granted earlier to the Opposite Parties to the case in the Hon'ble Delhi High Court allowing them to manufacture and sell drugs based on 'Linagliptin'. The order dated 29.03.2023 has been challenged by the Opposite Parties before the Division Bench of the Hon'ble Delhi High Court and matter is still pending.

29. The Commission notes that with respect to question of validity of Second Patent, a Revocation Petition bearing C.O. (Comm. IPD-PAT) No. 38 of 2022 was filed by the Informant before the Hon'ble Delhi High Court in terms of Section 64 (1) of the Patents Act, 1970 seeking revocation of Second Patent on the grounds, *inter alia*, that the First Patent covered the same compound, viz., 'Linagliptin'. In the said case, the interim application of the Informant was rejected by the Hon'ble Court *vide* order dated 27.07.2022. Thereafter, the Informant also filed a review application before the Hon'ble Delhi High Court, but the same was dismissed *vide* order dated 26.09.2022. The Revocation Petition is pending adjudication before the Hon'ble Delhi High Court.

30. The Commission is of the view that the question of validity of a patent may not be looked into by the Commission. This is a thicket which should be left untouched by the competition authority for want of subject matter competence, save to the extent specifically provided under the Act. Further, as per the established jurisprudence worldwide, in matters relating to frivolous and vexatious litigation resulting in alleged abuse of dominance, the competition authority is required to look into the matter objectively as to whether the litigation resorted to by the dominant entity is *ex facie* baseless, *i.e.*, no reasonable litigant could realistically expect success on the merits, and it is filed with the intent to prevent competition.

31. The Commission, based on above, is of the *prima facie* view that the aforementioned litigations initiated by the Opposite Parties cannot be, at this stage, said to be fraught with any lack of *bona fide*. Nothing further is germane to be said in the context of this issue, which is to be decided by the court of competent jurisdiction where the matter is pending.

32. The Commission, in the specific facts and circumstances of this case, is of the view that this may not be a fit case warranting an investigation and has thus obviated the requirement of defining a relevant market and assessing dominance of the Opposite Parties.

33. In view of the foregoing, the Commission is of the opinion that there exists no *prima facie* case and the matter is directed to be closed forthwith under Section 26(2) of the Act.

34. Before parting with the order, the Commission deems it appropriate to deal with the request of the Opposite Parties seeking confidentiality over certain documents/information filed by it under Regulation 35 of the Competition Commission of India (General) Regulations, 2009 (General Regulations). Considering the grounds put forth by Opposite Parties for the grant of confidential treatment, the Commission grants confidentiality to such documents/information in terms of Regulation 35 of the General Regulations read with Section 57 of the Act for a period of three years from the passing of this order. It is, however, made clear that nothing used in this order shall be deemed to be confidential or deemed to have been granted confidentiality, as the same has been used for the purposes of the Act in terms of the provisions contained in Section 57 thereof.

35. Notwithstanding the order passed above, the Commission particularly emphasizes that the findings reflect the views of the Commission purely from the standpoint of the provisions of the Competition Act, 2002 and may not be construed as expressing any opinion on merits in any manner in respect of other ongoing proceedings *inter se* the parties in any other court or forum.

36. The Secretary is directed to forward a copy of this order to the parties accordingly.

Sd/-
(Ravneet Kaur)
Chairperson

Sd/-
(Sangeeta Verma)
Member

Sd/-
(Bhagwant Singh Bishnoi)
Member

New Delhi
Date: 22.08.2023