$~66

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

Date of Decision: 22nd December, 2023

\+ **CS(COMM) 947/2023, I.As. 26255/2023, 26256/2023, 26257/2023, 26258/2023, 26259/2023, 26260/2023, 26261/2023 & 26262/2023**

KUDOS PHARMACEUTICALS LIMITED & ORS. ..... Plaintiffs

Through: Mr. Pravin Anand, Ms. Vaishali R Mittal, Mr. Siddhant Chamola, Ms. Pallavi Bhatnagar, Mr. Shivang Sharma, Advs. (M. 9999052646)

versus

DR REDDYS LABORATORIES LIMITED ..... Defendant

Through: Mr. J. Sai Deepak, Mr. Mohit Goel, Mr. Sidhant Goel, Mr. Aditya Goel and Mr. Deepankar Mishra, Advs. (M. 9716746496)

CORAM:
JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J.(Oral)

1. This hearing has been done through hybrid mode.

I.A. 26261/2023 (for exemption)

2. This is an application seeking exemption from filing originals/certified/cleared/typed or translated copies of documents, left side margins, electronic documents, etc. Original documents shall be produced/filed at the time of Admission/Denial, if sought, strictly as per the provisions of the Commercial Courts Act, 2015 and the DHC (Original Side) Rules, 2018.

3. Exemption is allowed, subject to all just exceptions.

4. Accordingly, the application is disposed of.

I.A. 26262/2023 (for court fee)

5. This is an application seeking extension of time in filing the court fee. The court fee be deposited within a week. Application is disposed of.

CS (COMM) 947/2023 & I.A. 26255/2023 (u/O XXXIX Rules 1 & 2 CPC), I.As. 26256-60/2023

6. Let the plaint be registered as a suit.

7. Issue summons and notice to the Defendant. Mr. Mohit Goel, ld. Counsel accepts summons and notice.

8. The present suit has been filed by the Plaintiffs-Kudos Pharmaceuticals Ltd., Astrazeneca AB and Astrazeneca Pharma India Ltd. against the Defendant-Dr. Reddy's Laboratories Ltd.

9. The present suit relates to the alleged infringement of the Plaintiffs' patent IN 228720 (*hereinafter, 'suit patent' or 'IN '720')*. The suit patent relates to the Plaintiffs' product comprising of 'Olaparib' sold under the brand name 'LYNPARZA'. The same is used for the treatment of ovarian cancer, breast cancer, pancreatic cancer and prostate cancer.

10. The Plaintiffs claim to hold a series of patents in respect of the said product Olaparib and other derivatives thereof - the details of which are as under:

i. **Markush Patent- IN 245218 titled *'Substituted Benzyl Phthalazinones'***

- Subject: The main claim of the said patent is a Markush structure, that covers a general group of oral PARP inhibitors.
- Other details are as follows:

Indian Application Number	611/DELNP/2003	(Genus Patent)
Patentee	KuDOS PHARMACEUTICALS LIMITED	
PCT application number	PCT/GB2001/04729	
PCT International Filing Date	October 25, 2001	
Priority date	March 12, 2001	
S. 11A Publication Date	March 20, 2009	
Date of Grant	January 7, 2011	
Date of Patent Expiry	October 25, 2021	

ii. Suit Patent: IN 228720 titled *'Phthalazinone Derivative'*.

- Subject: Relates to Olaparib specifically.
- Expires on 12th March, 2024.

Indian Application Number	3895/DELNP/2005	Compound patent (Species)
Patentee	KuDOS PHARMACEUTICALS LIMITED	
PCT application number	PCT/GB2004/001059	
PCT International Filing Date	March 12, 2004	
Priority date	March 12, 2003	
Date of filing in India	August 31, 2005	
S. 11A Publication Date	April 27, 2007	
Date of Grant	February 10, 2009	
Date of Patent Expiry	March 12, 2024	

iii. IN 275060 titled *'A Method Of Synthesising 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2h- Phthalazin-1-One'*

- Subject: Method of synthesis of Olaparib
- Expires on 15th October, 2027.

Indian Application Number	1539/DELNP/2009	Method of synthesis of Olaparib
Patentee	KuDOS PHARMACEUTICALS LIMITED	
PCT application number	PCT/GB2007/003888	
PCT International Filing Date	October 15, 2007	
Priority date	October 17, 2006	
S. 11A Publication Date	May 22, 2009	
Date of Grant	August 22, 2016	
Date of Patent Expiry	October 15, 2027	

iv.* IN 295417 titled *'Pharmaceutical formulation 514'

- Subject: A formulation patent of the tablet.
- Expires on 15th October, 2029.

Indian Application Number	514/MUMNP/2011	Pharmaceutical formulation
Patentee	KuDOS PHARMACEUTICALS LIMITED	
PCT application number	PCT/GB2009/051309	
PCT International Filing Date	October 5, 2009	
Priority date	October 7, 2008	
S. 11A Publication Date	December 23, 2011	
Date of Grant	April 3, 2018	
Date of Patent Expiry	October 5, 2029	

11. Regarding the Markush patent, no suit is currently pending. However, the suit patent is the subject matter of ***CS(COMM) 29/2023*** titled ***'Kudos Pharmaceuticals v. Natco Pharma Limited'***. Further, a revocation petition under Section 64(1) of The Patents Act, 1970 has also been filed titled ***'Natco Pharma Limited v. Kudos Pharmaceuticals***' bearing no. ***C.O.(COMM.IPD-PAT) 1/2023***. These two proceedings are stated to be pending before this Court.

12. It is averred that in May 2023, the Plaintiffs conducted independent investigations which revealed:

- From the Drugs Control Administration in Srinakulam, Andhra Pradesh, it was revealed that the Defendant obtained a Manufacturing License and Specific Export Permission for Olaparib, with operations based in Srikakulam District, Andhra Pradesh, India. The said license was stated to be valid up to 30th June 2023.
- The Defendant's website, *'api.drreddys.com'*, proclaims that they are a leading manufacturer and global supplier of Olaparib API. The

website identifies Olaparib API with the CAS Number 763113-22-0 and associates it with the Plaintiffs' brand ‘LYNPARZA’. The site explains the mechanism of Olaparib as an inhibitor of PARP enzymes (PARP1, PARP2, PARP3), detailing its role in cellular processes like DNA transcription, cell cycle regulation, and DNA repair.

13. Further, it is averred that an independent investigator conducted two telephonic investigations, first in June 2023 and then on 12th December 2023. During these calls, Customer Care Executives confirmed that the Defendant could supply bulk quantities of Olaparib API. The Defendant’s representatives provided this information initially, and it was reaffirmed during the second call on 12th December, 2023. It was also clarified that while the Defendant manufactures Olaparib in API form, they do not produce any finished formulation of it. Thus, in view of the above, it is contended that the Plaintiffs’ rights as provided under Section 48 of The Patents Act, 1970 have been violated by the Defendant.

14. Insofar as the present suit is concerned, and considering that the life of the patent extends only till 12th March, 2024, the Defendant is willing to give an undertaking that it does not intend to manufacture and sell the product Olaparib on a commercial scale.

15. However, it is currently manufacturing and exporting Olaparib for the purposes outlined in Section 107 A of The Patents Act, 1970, a fact that is also stated on the Defendant’s website.

16. Accordingly, ld. Counsel for the Plaintiffs submits that if the Defendant is willing to undertake that it will not commercially launch the product before 12th March, 2024, the suit can be decreed on those terms. This is subject to paragraph 111 of the decision of the ld. Division Bench in

Bayer Corporation v. Union of India (2019:DHC:2199-DB). The relevant extract of the said judgment is as follows:

> *"111. The approach of the learned single judge in permitting export, without any inquiry and holding that export of 1000 or 2000 tablets constituted reasonable use, in this case, cannot be countenanced. In such case, upon the patent proprietor alleging the infringement was to institute legal proceedings to injunct the alleged exporter or seller, it is equally possible for the seller or exporter to seek a declaration or appropriate relief (including in a suit for groundless threat, if such action lies) that its overseas sales are for research and purposes covered by Section 107A. This Court is of the opinion that the inquiry and adjudication in such cases would be in regard to the following:*
> *(1) The patent granted;*
> *(2) The nature of the product or elements sought to be exported;*
> *(3) The details of the party or party importing the product,*
> *(4) The quantity sought to be exported*
> *(5) Other particulars with respect to the end use of the product, to establish that it is solely for research and development of information to regulatory authorities in the other country;*
> *(6) All particulars regarding the relevant regulations, covering the kind and scope of inquiry, including the quantities of the product (i.e the patented product or compound, API or fine chemical needed). These details must be supplied by the exporter/seller of the product to the overseas buyer. In case the defendant is not the seller, it should disclose who had purchased the product in the relevant quantities, to facilitate its impleadment in the proceedings. In the event it cannot do so, the consequences of such result ought to be considered by the court.*
> *(7) If the regulations are in the language of that*

country, an authentic English translation to facilitate a speedy resolution;

(8) Appropriate interim order, including undertaking by way of affidavit to compensate the plaintiff, in the event the suit were to be decreed and the extent of such monetary compensation. The affidavit should be of an authorized personnel, and kept alive during the pendency of litigation, duly authenticated by the board of director or other controlling body of the defendant- and whenever the company or entity undergoes amalgamation or transfer, suitable undertaking from the successor organization;

(9) If necessary, verification through the Indian mission (and its trade division) abroad regarding the authentication of the third party and/ or its facilities abroad.

(10) If it is held by the court that the exporter is not involved in sale or export of any patented product, but a generic article, unprotected by patent law, when denying relief, suitable restitutionary relief should be awarded to the defendants in monetary terms, to preclude litigation that prevents trade or competition. The above aspects are only indicative of the matters that need examination, they are in no way exhaustive and the court may consider any other matter relevant to the subject."

17. On behalf of the Defendant-Mr. Sai Deepak, ld. Counsel submits that the Defendant is willing to give an undertaking that it would not commercially launch the product Olaparib prior to the expiry of the patent until then, it would only undertake activities which are permissible under Section 107 A of The Patents Act, 1970 in terms of the judgment mentioned above.

18. He further, submits that two further patents as provided above at paragraphs 10(iii) and 10(iv) are not being infringed by the Defendant.

19. Accordingly, after hearing ld. Counsels for the parties, insofar as the injunction which is sought, it is clear that there is no contest and, thus, the following directions are issued:

a) The Defendant shall stand permanently restrained from commercially launching any product consisting of Olaparib, Olaparib API or any other product except as permissible under Section 107 A in terms of paragraph 111 of ***Bayer Corporation (supra).***

b) Post the expiry of the patent on 12th March, 2024, the above embargo would cease automatically.

c) If, in the meantime, the suit patent is revoked in the above proceedings as provided in paragraph 11 above, or is held to be invalid and unenforceable then, in those circumstances too, the restraint would cease automatically.

20. The Plaintiffs have reserved their rights under Order II Rule 2 CPC in terms of paragraph 3 of the plaint. Needless to state, the rights and remedies, if any, of both parties are left open. No further reliefs are pressed.

21. The suit is decreed in the above terms. All pending applications are disposed of. Accordingly, let the decree sheet be drawn up.

PRATHIBA M. SINGH
JUDGE

DECEMBER 22, 2023
dj/dn

corrected & released on 26th December, 2023