

# MEDIATION FINALS

# IN THE MATTER OF AN ARBITRATION UNDER THE LCIA RULES (2014) BETWEEN

Egg Maggi Pharmaceuticals LLC

Claimant

- AND -

The Republic of Silverstone

Respondent

ARB Case No. ACT/03/2022

President: Mx. Hardik Malik, QC

Co-arbitrators: Dr. Tansa Shah, Dr. Neha Giridharan

**MEDIATOR'S BRIEF** 

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KKS & Associates LLP, Wisteria Lane, Hungaroring 119084.

**Subject**: Notice of Arbitration pursuant to Article 1 of the LCIA Arbitration Rules 2014 between Egg Maggi Pharmaceuticals and Republic of Silverstone

In accordance with Article 1 of the 2014 LCIA Arbitration Rules, Egg Maggi Pharmaceuticals (**Claimant**), a limited liability company incorporated under the laws of the Republic of Hungaroring, hereby submits its dispute (Dispute) with the Republic of Silverstone (**Respondent**) to arbitration.

# A. JURISDICTION

By submitting this Notice of Arbitration, Claimant accepts Respondent's standing offer to arbitrate made in Article X of the Hungaroring-Silverstone Bilateral Investment Treaty 2007 (BIT):

- 1. Disputes related to Investments, which concern an alleged breach of an obligation under this Treaty shall, if possible, be settled amicably.
- 2.If such disputes cannot be settled according to the provisions of paragraph (1) within a period of three months from the date on which either party to the dispute requested amicable settlement, the Investor party to the dispute may submit the dispute to an arbitral tribunal established in accordance with the LCIA Arbitration Rules 2014. Each Contracting Party hereby gives its unconditional consent to the submission of a dispute to international arbitration or conciliation in accordance with the provisions of this Article.
- 3. The parties to the dispute shall not be precluded from pursuing mediation at any point of these arbitral proceedings, including the time after the award is issued by the arbitral tribunal.

The dispute was notified to Respondent on 25th December, 2021 and there has been no effort on part of the Respondent to pursue amicable settlement. Pursuant to the lapse of the three month period, this notice to arbitrate is submitted.

# **B. SUMMARY OF RELEVANT FACTS**

The dispute in the instant case arises out of the Respondent's abrupt issuance of a Compulsory Licence against the Claimant's patented drug, EyeDropit.

Claimant is a renowned pharmaceutical company, headquartered in Wisteria Lane, Hungaroring. It specialises in R&D and manufacture of drugs for combating tropical and highly transmissible diseases. It has operations in over 10 countries across the world. Respondent is a low-income HDI country situated in South-East Asia. By virtue of its tropical climate, several tropical diseases have ravaged the country's population over the last few decades. These diseases were particularly lethal for children, as is evidenced by their high Child Mortality Rate. Respondent has several domestic players in the pharmaceutical industry, but these companies have struggled with developing effective drugs against a large number of tropical diseases.

In 2009, realising that Silverstone would be a fruitful market for its commercial ventures, Claimant established a wholly-owned subsidiary company named Chilli Maggi Pharma (CMP) to explore the option of setting up a Research and Development (R&D) unit in Silverstone to develop drugs to tackle several tropical diseases, with a focus of diseases targeting children. In mid-2010, CMP opened its first R&D unit in the city of Hoover, Silverstone. Given the expertise and technical know-how possessed by CMP, the R&D team made rapid progress in their research and was able to develop several drugs for clinical trials within 2 years of its establishment. Upon seeing initial successes in their clinical trials, CMP made further investments into Silverstone for setting up drug manufacturing units in Hoover and the coastal city of Kneedi.

By mid-2015, CMP had overwhelming successes in its clinical trials and had also received approval from the Silverstone Food and Drug Administration for 3 drugs – ChickEnv for tropical chicken pox, DoraMed for the fatal explorer syndrome and EyeDropit for a fungal eye infection that blinded children. These drugs showed high efficacy in the clinical trials and proved promising to alleviate the perils of Silverstone children. The manufacturing process for these drugs commenced and they were introduced in the Silverstone markets by the first quarter of 2016. The drugs proved very successful and had a high efficacy rate in children aged between 6 and 14 years old. At the time of the launch, the drugs were priced at approximately \$90 per dose of the medicine. CMP also obtained registered product patents for each of these drugs with the Silverstone Patent Office in Hoover in late 2017.

By 2018, other players in the market had also developed medicines to treat the eye infection. However, their efficacy was questionable in comparison to the drugs manufactured by CMP.

CMP had also launched several other medicines, but EyeDropit and DoraMed accounted for roughly 80% of their sales in Silverstone. Due to an increase in cost of production based on raw materials and transportation costs, the costs of these medicines were increased to \$110 per dose. These medicines were highly effective, but proved to be rather costly for consumers to purchase. Some consumers had switched to the other drugs manufactured by the other players due to the high costs, but Claimant's drugs continued to remain medically recommended.

In late 2019, Silverstone suffered a devastating wave of the tropical eye infection that led to the death of over 2000 children in three months. Most of these deaths occurred due to the lack of medicines in the market, because the pharmaceutical companies had not anticipated such demand. The Republic of Silverstone declared this to be a public health emergency. CMP immediately ramped up its production to meet the increased demand, such that both its manufacturing units in Silverstone halted the production of other drugs and only produced EyeDropit. On 23rd May 2020, the Patent Office of Silverstone passed an order granting a compulsory licence for the manufacture, use and sale of EyeDropit to domestic manufacturers in Silverstone in the wake of the medical crisis of the eye infection. The order stated that the high price of the drug made it unaffordable for a large part of the Silverstonian population and even with the increased production by CMP, they were unable to meet the demand of the public health emergency. This compulsory licence did not specify the time period for which the licence was granted and fixed the royalties to be paid to CMP at \$6 per dose.

CMP appealed this order to the Supreme Court of Silverstone, stating that the issuance of Compulsory Licence was did not satisfy the requirements of domestic law, and was discriminatory because it was only passed against EyeDropit and not against other substitute drugs. The Supreme Court of Silverstone upheld the order passed by the Patent Office. Other domestic players started to produce EyeDropit and sell it at \$60 in the market. CMP was regularly paid its royalties by the other players, but because of the lower price at which EyeDropit was sold in the market, CMP suffered severe losses.

By November 2020, the health emergency had died down - largely because CMP and other pharmaceutical companies had worked in collaboration to develop a vaccine providing better immunity against the infecting fungus. This vaccine was a success and on 19th November 2020, the Republic of Silverstone declared an end to the public health emergency. Subsequently, CMP approached the Patent Office for the revocation of the compulsory licence on EyeDropit, since the health emergency was over and CMP wanted to stop third parties from selling their drugs in the market. Additionally, the low prices and meagre royalties had taken a toll on CMP's profitability. The application for revocation was rejected by the Patent Office, stating that the drug was too expensive and it was necessary to issue the compulsory licence in public interest. This order was appealed by CMP, but it was upheld by the Supreme Court of Silverstone.

CMP found it unsustainable to continue operating in Silverstone if the compulsory licence on EyeDropit was not revoked because it affected their sales and profit margins. Due to the

decreased revenue, they had insufficient resources to devote to R&D for other drugs. Further, the shareholders of CMP felt that if Silverstone were to pass more compulsory licences against other drugs, their business would become unprofitable. After repeated requests with the patent office and the government, finding it unable to continue operations in this hostile business environment, CMP shut its R&D unit and its two manufacturing plants in Silverstone in February 2021. These units continue to remain non-operational till the date of this notice.

In commercial and business interest, CMP's entire business and their legal rights and obligations was taken over by its parent company, the Claimant. CMP has now ceased to exist. Resultantly, Claimant brings this claim against the Respondent under the Treaty for violations of its substantive obligations. The issuance of compulsory licence against CMP's drug amounted to indirect expropriation. The non-payment of fair compensation, the disproportionate measures adopted by failure to revoke the compulsory licence even after the health emergency was over and the discriminatory nature of the compulsory license breached Respondent's obligations under the Treaty. As a result of these actions, CMP has suffered losses to the tune of \$300 million due to lost profits and for having to share its technical know-how with its competitors. Having bought all the business and claims from CMP, Claimant now seeks compensation for these losses and damages from the Respondent.

## C. NOMINATION OF ARBITRATOR

Claimant hereby nominates Dr. Tansa Shah as their party appointed arbitrator.

### D. PRAYER FOR RELIEF

In light of the above. Claimant hereby respectfully requests the Arbitral Tribunal to:

- 1.DECLARE that Respondent has indirectly expropriated Claimant's investment (their intellectual property) and breached Article II of the BIT;
- 2. ORDER Respondent to pay Claimant compensation amounting to no less than \$300 million for lost profits and \$100 million in damages, plus interest as of the date of violation;
- 3.ORDER Respondent to compensate Claimant for all of their costs in this Arbitration and to bear alone the costs of the Tribunal.

Respectfully submitted,
For and on behalf of Claimant,
Aditya K. Singh and Ritu Kumari,
KKS & Associates LLP.

HimShank & Co. LLP, Cabo Costa Avenue, Hoover, Silverstone 678909

**Sub**: Respondent's Response to the Notice of Arbitration under Article 2 of the LCIA Arbitration Rules 2014

As required under Article 2 of the LCIA Rules 2014, the Republic of Silverstone (**Respondent**) hereby presents its Response to the Notice of Arbitration in relation to the ARB Case. No. ACT/03/2022 filed by Egg Maggi Pharmaceuticals (**Claimant**).

Respondent hereby rejects the jurisdiction of this Tribunal and rejects all claims raised by the Claimant in its Notice of Arbitration. Notwithstanding the jurisdictional objection, Respondent also raises a counterclaim against Claimant for violating their obligations under Article VII of the Hungarorian-Silverstone Bilateral Investment Treaty 2007 (**BIT**).

# A. CLAIMANT HAS NO STANDING

The alleged investment in this case is the intellectual property relating to EyeDropit and the investment relating to the business of CMP in Silverstone. Claims against Respondent for violating the treaty with respect to these investments can only be brought by Chill Maggi Pharmaceuticals, which has now ceased to exist. By purchasing their business, Claimant does not automatically get the right under the BIT to sue Respondent for breach of the BIT because these claims arose before the Claimant bought the business. Respondent is a separate entity and has not made any investment into the Respondent State after taking over the business and thus, does not qualify as an investor under the Treaty.

# B. RESPONDENT HAS NOT INDIRECTLY EXPROPRIATED CMP'S INVESTMENT

Notwithstanding the jurisdictional objection, Respondent alleges that they have not violated the BIT as the issuance of the compulsory licence does not amount to indirect expropriation.

Under the BIT, in order for a government action to result in indirect expropriation, the investment should be destroyed or the owner should be absolutely deprived of its ability to manage, use or control its property in a meaningful manner. In the instant case, the compulsory licence was issued against only one of the drugs manufactured by CMP in light of a public health crisis. This compulsory licence did not prevent CMP from manufacturing its own drug, but allowed increased production at a cheaper price to ensure availability of the drug in the Silverstone market. The action was taken in public interest, in accordance with due process and was accompanied by payment of royalties as compensation which were timely paid by the manufacturers in question. The alleged measure was only taken against CMP because their

drug was the most efficacious against battling the eye infection. There were several research papers that attested to the higher efficacy of EyeDropit against the deadly fungus, which meant that the measure was not discriminatory as different market players were not in similar positions. The alleged measure was a valid exercise of regulatory power, in compliance with the Respondent's obligations under the BIT.

Further, the issuance of a compulsory licence against one of multiple drugs manufactured by CMP does not completely deprive them of their investment in the Respondent State. CMP had patent protection for several other drugs that they manufactured, marketed and sold in the Respondent State. Thus, there was no deprivation of the investment by the alleged action.

# C. THE ALLEGED ACTION FALLS WITHIN THE AMBIT OF THE REGULATORY EXCEPTION IN ARTICLE VII OF THE BIT

Article VII of the BIT exempts any state action from violating any provision of the BIT that is taken in public interest, public health or emergencies, provided the measure is proportionate and necessary for the objective. In the instant case, the compulsory licence was issued because there was a public health emergency that had claimed the lives of over 2000 young children. The drug in question was the most efficacious remedy against the infection, but was unaffordable for over 80% of the Silverstonian population. Thus, in public interest, the compulsory licence was issued in accordance with the domestic patent law and royalties were fixed at a reasonable rate. Thus, the alleged action falls within the scope of the exemption provision of the treaty.

# D. COUNTERCLAIM FOR VIOLATION OF INVESTOR'S OBLIGATIONS UNDER THE BIT

Respondent claims that CMP has violated its obligations under Article VII of the BIT by violating the domestic laws relating to environmental protection and waste management. In October 2019, a surprise inspection was conducted at CMP's manufacturing plant at Kneedi, where it was found that CMP was discharging untreated toxic medical wastes into the nearby water body in violation of domestic environmental legislations. When issued a show-cause notice, CMP denied all allegations and a detailed investigation was undertaken of the samples from the manufacturing plant. The investigations found CMP guilty of discharging toxic waste into the sea. However, before any punishment could be imposed, the public health crisis broke out. However, the initial assessment stands true and thus, CMP violated domestic legislation in relation to its investment. Thus, Respondent claims damages worth \$100 million from Claimant for violation of environmental regulations and consequent damage to the environment in Silverstone, in lieu of the fine to be imposed by the investigation authority. Respondent would like to confirm that this counterclaim before the Tribunal does not preclude

their right to pursue the fines for environmental violations independently, in the event the counterclaim is not adjudicated upon.

# E. APPOINTMENT OF ARBITRATOR

Respondent would like to nominate Dr. Neha Giridharan as their party-appointed arbitrator.

## F. PRAYER FOR RELIEF

In light of the above, Respondent respectfully requests the Arbitral Tribunal to find that:

- 1. It has no jurisdiction over the present claim as Claimant has no standing in the instant case;
- 2. If the Tribunal finds that it has jurisdiction to adjudicate upon these claims,
  - a) The issuance of compulsory licence did not amount to indirect expropriation and if it amounted to expropriation, the expropriation was not unlawful;
  - o b) The alleged measure falls within the ambit of the regulatory exception.
- 3. Claimant violated their obligations under Article VII of the BIT and is liable to pay \$350 million to Respondent.

Respectfully submitted,
For and on behalf of Respondent,
Himanshu Kumar and Shashank Tewari
HimShank & Co. LLP.

# PROCEDURAL ORDER NO. 1

### Of 23rd March 2022

# In the Arbitral Proceedings

Egg Maggi Pharmaceuticals v. The Republic of Silverstone (ACT/03/2022)

Following the receipt of the file from LCIA, and upon reviewing the notice and response to arbitration, the Arbitral Tribunal held a telephone conference with both parties on 19th March 2022 discussing further conduct of the proceedings.

In light of the discussions, the Arbitral Tribunal hereby makes the following orders:

In their next set of submissions, the parties are requested to address the following issues:

- 1. Does the Claimant have standing before the arbitral tribunal in this case?
- 2. Did the issuance of compulsory licence against CMP's drug, EyeDropit, amount to indirect expropriation under the BIT?
- 3. If (b) is answered positively, does the impugned act fall within the regulatory exception under Article VII of the Treaty?
- 4. Is Claimant liable for breaching their obligations under the BIT by violating domestic environmental legislations?

The timetable for the submission of written arguments is annexed to this order (OMITTED). This Procedural Order does not preclude the parties from amicably settling the dispute. However, any intention to amicably resolve the dispute must be communicated to the Tribunal promptly. Any amicable settlement arrived at between the parties will be reviewed by the Tribunal and passed as an award if it is in accordance with the BIT and other international law norms.

For the Arbitral Tribunal, Mx. Hardik Malik, QC Presiding Arbitrator.

# PROCEDURAL ORDER NO. 2

Of 7th April 2022

# In the Arbitral Proceedings

Egg Maggi Pharmaceuticals v. The Republic of Silverstone (ACT/03/2022)

Following the receipt of a request from Egg Maggi Pharmaceuticals to refer the dispute to investor-state mediation, the Tribunal communicated said request to the Respondent, who has accepted the same.

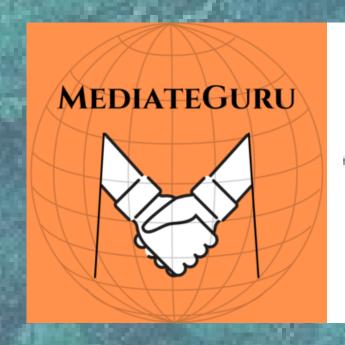
Consequently, this Tribunal refers the parties to mediation to be conducted at the VII NLS NMC 2022, on Monday, 2nd May 2022 at 14:00 IST. The Parties are not obligated to restrict their discussion to the issues outlined in P.O.1 and are free to discuss matters outside of the outlined issues. However, in terms of passing the award, the Tribunal shall only convert those aspects of the settlement into an award over which it has valid jurisdiction.

On Behalf of the Arbitral Tribunal,

Mx. Hardik Malik, QC Presiding Arbitrator.

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