**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| BELCHER PHARMACEUTICALS, LLC,<br><br>Plaintiff,<br><br>v.<br><br>HOSPIRA, INC.,<br><br>Defendant. | C.A. No. 17-cv-775-LPS |

**EXPERT REPORT OF SHYAM MOHAPATRA, PH. D., IN SUPPORT OF BELCHER PHARMACEUTICALS, LLC'S INFRINGEMENT POSITION**

I, Shyam Mohapatra, Ph.D., declare as follows:

## I. Background and Qualifications

### a. Credentials

1. I am a Distinguished Professor at the University of South Florida ("USF") Institute for Advanced Innovation and Discovery and the Associate Dean of Graduate Programs at USF College of Pharmacy. Over the past 20 years, I have assisted in numerous scientific publications, with topics ranging from drug delivery methods to anti-cancer treatments. I have over 40 US patents and patent applications, some of which include methods of drug delivery and drug compositions for treating infections.

2. I received my Ph.D. at Australian National University in Canberra in Botany in the field of Genetics in 1984. Prior to this, I received a Master's Degree in Genetics from G.B. Pant University of Agriculture and Technology in Pantnagar, India in 1978, and my Bachelor of Science Degree from Orissa University of Agriculture and Technology in

Bhubaneswar, India in 1976. Following my Ph.D. I trained in Genomics Sciences in Bielefeld, Germany, then worked as Research Associate at the McGill University, Montreal, Canada and then appointed as Assistant Professor and then Associate Professor in Immunology, at the University of Manitoba, Winnipeg, Canada during 1988 to 1995. In 1996, I became an Associate Professor in Internal Medicine at the University of South Florida ("USF"). I also received my Masters in Business Administration from USF in 1999. At USF, I became a full professor in 2000 and awarded a Distinguished Health Professor in 2011.

3. I am also currently a Distinguished Professor at the USF Institute for Advanced Innovation and Discovery, Director of the USF Center for Research and Education in Nanobioengineering, Director of the Division of Translational Medicine for the Department of Internal Medicine at the USF Morsani College of Medicine, and a Research Career Scientist and Principal Investigator for the James A Haley VA Hospital in Tampa, Florida.

4. I have also served as the Associate Dean of Graduate Programs and a professor of Pharmaceutical Sciences at the University of South Florida College of Pharmacy since 2013. I teach both undergraduate and graduate courses in cellular and molecular immunology, medicine, and pharmacy at the University of South Florida. I have authored or co-authored over 200 research papers, reviews, and book chapters. I regularly act as referee for a variety of journals in the fields of medicine, pharmacy and engineering and specialized areas such as molecular medicine and pharmacy, among others. I have been a reviewer of such journals as Biodrugs, Pharmaceutical Sciences, Genetic Vaccines and Therapy (Editor-in-Chief Molecular and Clinical Allergy), Associate Editor Gene Therapy (Nature Journals) Mucosal Immunity, Journal of Allergy and Clinical Immunology, Immunology Today, Journal of Clinical

Investigations, International Journal of Cancer, Allergy Journal of Immunology Journal, International Archives of Allergy and Immunology and others.

5. I have regularly spoken to the medical and pharmacy community and lectured at universities throughout the country on a variety of topics in related fields.

6. My industry experience includes working as a consultant and performing contract research over more than 25 years. I have consulted with industries on an as-needed basis in the areas of pharmaceutical biotechnology and nanotechnology. For example, I have consulted with industries such as Connaught Labs, Merck, AstraZeneca, Bristol Myer Squibb, Genetics Institute and others involving the development and formulation of pharmaceutical drug products. I was personally involved in post-marketing research and development projects and large-scale manufacture of pharmaceutical drugs, when I did this consulting work.

7. I was previously a member of the Canadian Society of Allergy and Immunology and the European Academy of Allergology and Clinical Immunology. I am a Fellow of the American Academy of Allergy, Asthma and Clinical Immunology and an Honorary Member of the Mexican Society of Allergy and Immunology, the USF Academy of Inventors, the American Thoracic Society, the American Academy of Allergy and Clinical Immunology, the American Association of Immunologists and American Association of Pharmaceutical sciences. I have been elected as a Fellow of several Learned Societies, including the American Association for the Advancement of Science (AAAS), the National Academy of Inventors, the American Institute of Medical and Biological Engineers and a Fellow of the prestigious National Academy of Inventors.

8. I have received national and international recognition for my contributions to the development and characterization of pharmaceuticals in the immunological and allergy

field, excipients and solid materials, including being the recipient of prestigious Alexander Von Humboldt Research Fellowship, Bonn, Germany; The Pharmacia Allergy and Immunology Foundation, Upsala, Sweden; The Global Corporate Award in Nanotechnology and was inducted to the 'Florida Inventor Hall of Fame' for contributions to biomedical and pharmaceutical nanotechnology.

9. I have 36 granted U.S. Patents as well as a number of pending applications. These patents generally concern immunotherapy, methods of gene transfer, and prevention of viral diseases, novel diagnostic methods, novel devices for treatment, discovery of anti-inflammatory and anti-cancer, anti-viral and anti-bacterial drugs, methods of treatment of diseases, and novel drug formulation methods.

10. Additional information about my credentials are listed in my curriculum vitae attached as Exhibit A.

**b. Compensation**

11. I am being compensated at a rate of $450 per hour plus expenses for my consulting services. My compensation is not contingent on the opinions expressed in this declaration, my testimony at deposition or trial, or the outcome of this case.

## II. Opinions to Be Expressed

**a. Retention & Assignment**

12. I have reviewed U.S. Patent No. 9,283,197 ("the '197 Patent") and its prosecution history. The '197 Patent is attached as Exhibit B to this declaration. I have also reviewed Hospira's NDA No. 20-9359 ("the Hospira NDA") as well as Judge Stark's 9/28/18 Claim Construction Ruling (D.I. 97).

13. I have been asked by counsel to provide my opinions in this case regarding Hospira's infringement of the '197 Patent.

**b. Legal Standards**

14. I understand that, in order to infringe a patent in the United States, an actor must perform each element of a claim within a patent either literally or under the Doctrine of Equivalents.

15. I understand that the Doctrine of Equivalents is a legal rule that allows a court to hold a party liable for patent infringement even though the infringing device or process does not fall within the literal scope of a patent claim, but nevertheless is equivalent to the claimed invention.

16. I understand that any analysis done under the Doctrine of Equivalents is applied to individual claim limitations and not the invention as a whole. Infringement may be found under the Doctrine of Equivalents if every limitation of the asserted claim, or its "equivalent," is found in the accused subject matter, where an "equivalent" differs from the claimed limitation only insubstantially. One way of determining whether a claim limitation has been met under the Doctrine of Equivalents is called the "triple-identity" test. Under the triple-identity test, the difference between the feature in the accused device and the limitation literally recited in the patent claim may be found to be equivalent if the feature in the accused device: 1) performs substantially the same function, 2) In substantially the same way, and 3) to yield substantially the same result as the limitation literally recited in the patent claim. What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case.

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