UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MOTIF FOODWORKS, INC.,

Petitioner,

v.

IMPOSSIBLE FOODS INC.,
Patent Owner.

Inter Partes Review No. 2023-00209

DECLARATION OF DR. CARL BATT IN SUPPORT OF PETITIONS FOR *INTER PARTES* REVIEW OF U.S. PATENT NOS. 9,943,096, 10,039,306, 11,013,250, 11,224,241

I, Dr. Carl Batt, Ph.D., declare as follows:

I. INTRODUCTION

1. I have been retained by Quinn Emanuel Urquhart & Sullivan LLP on behalf of Motif Foodworks, Inc. ("Petitioner" or "Motif") as an independent expert in these inter partes review ("IPR") proceedings which are pending before the Patent Trial and Appeal Board ("the Board") of the United States Patent and Trademark Office (the "Proceedings").

1. I understand that, in these Proceedings, Motif is challenging the validity of claims 1-12 and 14-24 of U.S. Patent No. 9,943,096 (the "'096 patent"), claims 1, 3–11, 13–14, 16–24, 26–27, and 29–33 of U.S. Patent No. 10,039,306 (the "'306 patent"), claims 1, 3-13, and 15-23 of U.S. Patent No. 11,013,250 (the "'250 patent"), and claims 1-23 of U.S. Patent No. 11,224,241 (the "'241 patent") (collectively, the "Challenged Patents" and "Challenged Claims"). Based on my review of these patents, I understand them to be assigned to Impossible Foods Inc. ("Patent Owner").

2. I am informed that the Challenged Patents have been asserted by Patent Owner against Motif in the co-pending litigation *Impossible Foods Inc. v. Motif Foodworks, Inc.*, Case No. 22-cv-311 (D. Del.) ("Litigation"). I understand that the Litigation is proceeding in the District Court for the District of Delaware ("District Court").

3. I understand that in the Proceedings, Motif is relying on U.S. Patent Publication No. 2011/0287467 ("Crane") (EX1014) as an asserted reference to demonstrate unpatentability of the claims of one or more of the Challenged Patents.

4. I have been asked to consider whether Crane should be considered "analogous art" to the subject matter claimed in the Challenged Claims.

II. QUALIFICATIONS

5. Exhibit 1008 is a true and correct copy of my current CV, which describes my education, patents and publications, employment and research history, and professional activities and awards. The following is a summary of my qualifications and professional experience.

6. I have over 35 years of experience in microbiology, molecular biology, protein engineering, cell culture and food science. In 1975, I was awarded a Bachelor of Science degree in Microbiology from Kansas State University in Manhattan, Kansas. In 1981, I was awarded a Doctor of Philosophy Degree in Food Science from Rutgers University in New Brunswick, New Jersey. I was a postdoctoral research associate from 1982-1984 in the Department of Nutrition and Food Science and a research scientist from 1984-1985 in the Department of Applied Biological Sciences at Massachusetts Institute of Technology in Cambridge, Massachusetts.

7. In 1985, I joined the faculty of Cornell University as an Assistant Professor in the Department of Food Science, where I was promoted to Associate Professor in 1991, and promoted to Professor in 1998.

8. While at Cornell University, I founded the Cornell University/Ludwig Institute for Cancer Research Partnership and served as its Director from 1999-2011. As Director, I managed the design, construction and operation of a Good Manufacturing Practice ("GMP") facility on the Cornell University Ithaca campus, which resulted in the production of recombinant proteins using microbial expression systems, including *Pichia pastoris*, that have been used in clinical trials.

9. I have conducted research in several areas that span the life and physical sciences. My work includes pioneering efforts in the fields of microbiology, molecular biology and nanotechnology. One area of research that I have focused on is the use of protein engineering and expression systems for producing recombinant anti-cancer therapeutics and proteins in general. For the past 34 years, my laboratory has been engaged in protein expression using a variety of host systems including bacteria, yeast, fungi and higher eukaryotic cells. Our work in *P. pastoris* began in the early 1990's and documented in publications expressing various proteins using this versatile expression system.

10. The major area of research currently underway in my laboratory concerns exploring parallel routes for the expression of therapeutic agents and

constructing rational approaches to scale-up of these systems. Our major focus is on the development and optimization of microbial-based expression systems for tumor antigens and tumor-specific antibody fragments. Our Biologics Production Facility enables us to carry out large-scale production of highly-purified immunotherapeutics suitable for early-phase human clinical trials.

11. Over the course of my career, I have authored or co-authored more than 300 peer-reviewed articles, book chapters and reviews. I have given more than 100 invited lectures worldwide. I am a named inventor on three United States patents.

12. I served as Chief Editor for Food Microbiology (1987-2000), a peer-reviewed journal. I also served as Editor for the Encyclopedia of Food Microbiology (1996-1999) and Chief Editor of its 2nd Edition (2009-2015). I served as Editor of Elsevier's Food Microbiology, Food Science Reference Module (2015-2016). I have also been on the Editorial Boards of the peer-reviewed journals: Food Biotechnology (1987-1992), Journal of Food Science (2001-2008), and Protein Expression and Purification (2001-2004).

13. I have been fortunate to receive a number of distinctions during my career. In 1990, I was awarded the Samuel Cate Prescott Award from the Institute of Food Technologists which is given to the outstanding scientist in my field under the age of 35. In 2000, I was named a Liberty Hyde Bailey Professor in the College of Agriculture and Life Sciences, a named chair created to honor the most

outstanding faculty in the college. It is an honor that I hold for the time I am on the Cornell faculty. Today that distinction is held by only five professors among the 1,629 faculty at Cornell University.

14. I am co-founder of the Nanobiotechnology Center ("NBTC") at Cornell University, a National Science Foundation supported science and technology center, and was co-Director of NBTC from 1999-2004. I am also co-founder of Main Street Science, a not-for-profit corporation established to develop and distribute K-12 science learning materials, and the founder of Nanooze, a science magazine for children.

15. In 2007, I was named a NSF Discovery Corps Fellow in recognition of both my extraordinary research accomplishments and my efforts to communicate advances in science and technology to the general public. In addition, I have been the recipient of a number of awards from Cornell University for teaching (Teaching Excellence Award, 1990), service (Faculty Fellows in Service, 2001; Kaplan Family Distinguished Faculty Fellowship in Service-Learning, 2003), and diversity (CALS Kathy Berggren Diversity and Inclusion Award, 2008).

16. In addition to my teaching responsibilities, I have mentored over 50 graduate students including 45 PhDs and over 100 undergraduates in my laboratory, many of whom now hold significant positions in academia, government and the private sector, both in the United States and internationally.

17. As a champion of making scientific concepts understandable for the general public, especially young students, I lead a team that developed a series of public exhibitions including "It's a Nanoworld," which was on a five-year tour in the United States after a six-month residency at EPCOT in Walt Disney World, and "Too Small To See," which is also on tour after opening in EPCOT in 2007. Subsequently I designed and oversaw the construction of two additional exhibits, "Take a Nanooze Break" (2010-2020) and "Nanooze Labs" (2011-2014) that were on exhibit at Walt Disney World and Disneyland respectively.

III. SCOPE OF ASSIGNMENT

18. I have been asked to evaluate whether Crane is analogous art for purposes of the Proceedings. In forming my opinions, I have considered Crane's specification(s), including the Abstract, the figures, and the claim language itself, as would have been understood by a person having ordinary skill in the art. I have also reviewed any other material cited in this Declaration.

19. In forming my opinions, I have relied on my personal knowledge and professional experience in researching, studying, developing, or using recombinant protein expression technology, and on the documents and information referenced in this Declaration.

20. This Declaration explains, based on facts and information available to me to date, the subject matter and opinions related to the Proceedings. As such, I

am prepared to provide expert testimony regarding opinions formed resulting from my analysis of the issues considered in this Declaration if called upon to do so by the Board or by the parties' attorneys. Additionally, I may discuss my own work, teachings, and knowledge of the state of the art in the relevant time period. I may rely on handbooks, textbooks, technical literature, and the like to demonstrate the state of the art in the relevant period and the evolution of relevant technologies.

21. Throughout this Declaration, I refer to specific pages of Crane and other documents. The citations are intended to be exemplary and are not intended to convey that the citations are the only source of evidence to support the propositions for which they are cited. I reserve my right to amend or alter my analysis and opinions in response to positions the Patent Owner may take or upon the discovery of new information.

22. I am being compensated at my customary consulting rate of $375 per hour for the time I spend on this matter. My compensation is in no way contingent on the nature of my opinions or the outcome of this or any other proceeding. I have no other financial interest in this proceeding. All of the opinions expressed in this Declaration are my own.

IV. LEGAL UNDERSTANDING

23. In this section I describe my understanding of certain legal standards that I have relied upon in forming my opinions set forth in this Declaration. I have

been informed of these legal standards by Motif's attorneys. I am not an attorney and I have not thoroughly studied the relevant patent law. I am relying only on instructions from Motif's attorneys for these legal standards.

A. Person of Ordinary Skill in the Art

24. I am informed that patent validity is determined from the perspective of a person of ordinary skill in the pertinent art at the time of the invention ("POSITA"). I understand that a POSITA is a hypothetical person who is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity—not an automaton.

25. In deciding the level of ordinary skill in the art, I am informed that the following factors may be considered:

- the levels of education and experience of persons working in the field;
- the types of problems encountered in the field; and
- the sophistication of the technology.

B. Section 103 and Analogous Art

26. I understand that, under 35 U.S.C. § 103, a person is not entitled to a patent if the claimed subject matter as a whole would have been obvious to a POSITA before the effective filing date of the claims.

27. In order for a reference to be properly used in an obviousness rejection under Section 103, the reference must be "analogous art" to the claimed invention. I understand that a reference (such as Crane) can be considered analogous art to

claimed subject matter if the reference is from the same field of endeavor as the claimed subject matter, even if it addresses a different problem. I also understand that a reference can be considered analogous art if the reference is reasonably pertinent to the problem faced by the named inventors, even if it is not in the same field of endeavor as the claimed invention.

V. CRANE

28. Crane is generally directed to methods using a recombinant host to produce functional, heme-binding proteins with complete heme incorporation, and purified preparations of the same. EX1014(Crane), Abstract. The methods of the Crane invention involve "co-expressing a recombinant heme binding protein and recombinant ferrochelatase protein, or polypeptide thereof, under conditions effective for complete heme incorporation into the recombinantly produced heme binding protein, thereby producing a functional heme-binding protein." *Id.*, [0009]; *see generally id.* [0009]-[0014]. Accordingly, "[t]he present invention is a straightforward and inexpensive method for high fidelity incorporation of heme into recombinantly overexpressed heme proteins," as "[c]o-expression of just one native protein, ferrochelatase (FC), in the presence of δ-ALA is sufficient to achieve 100% heme incorporation into three unrelated h[e]me proteins derived from different organisms." *Id.*, [0014].

29. Crane teaches that its methods are generally applicable to various classes of heme-binding proteins, including hemoglobins such as leghemoglobin. *Id.*, [0021]. For example, Crane recites (*id.*, [0021]):

> The various classes of heme-binding proteins that are encompassed by the methods of the present invention include, without limitation, globins (e.g., hemoglobin, myoglobin, neuroglobin, cytoglobin, leghemoglobin), [and] cytochromes (e.g., a-, b-, and c-types, cd 1-nitrite reductase, cytochrome oxidase), …..

30. According to the specification, "these proteins are completely functional and are more suitable for research, clinical, and commercial applications." *Id.*, [0024].

31. Crane teaches various systems that can be used to produce heme-proteins:

> Many different types of cells may be used to express heterologous proteins. Such as bacterial, archaeal, yeast, fungal, insect, vertebrate (such as mammalian cells), and plant cells, including primary cells and immortal cell lines.

Id., [0036].

> Fungal protein expression systems can also be utilized in the methods of the present invention to efficiently produce a functional recombinant heme-binding protein. Fungal species are considered safer than animal cells because they pose little risk of contamination by viruses, prions, or endotoxins. Additionally, fungal systems are more efficient and economical than mammalian expression systems. There are several

> fungal species which have been used as hosts for the expression of recombinant proteins, including, without limitation, yeast (e.g., *Pichia pastoris, Kluyveromyces lactis*, and *Saccharomyces cerevisiae*), soil fungus (e.g., *Trichoderma reesei*), and black mould fungus (e.g., *Aspergillus niger*).

Id., [0043].

32. Crane's expression systems also produce heme-containing proteins that are "isolated" (as that term is understood by POSITA). For example, Crane teaches that its "invention relates to a purified preparation of recombinant functional heme-binding protein." *Id.*, [0060]. Crane teaches:

> The purity of the preparation is assessed by the presence or absence of un-metallated heme, which can be measured by fluorescence spectroscopy and resonance Raman spectroscopy. In a preferred embodiment of the invention, the purified preparation of functional, recombinant heme-binding protein of the present invention is not fluorescent when excited at a wavelength of 397 nm and has a resonance Raman spectrum showing no evidence of free-base porphyrin incorporation.

Id., [0061]. In one non-limiting example, Crane describes how select heme-containing proteins were isolated "to >95% purity." *Id.*, [0075].

VI. CRANE IS ANALOGOUS ART TO THE CHALLENGED PATENTS

33. In my opinion, Crane is analogous art to the Challenged Patents. A POSITA for the Challenged Patents would have considered Crane to be part of the

same field of endeavor as the Challenged Patents and reasonably pertinent to the general problem of creating meat replicas, or components for such products, from non-animal sources.

34. As explained below, the advantages of using recombinant technology to produce food-grade ingredients and their products were well understood by 2013. Accordingly, a POSITA of the Challenged Patents would look to Crane to create products intended to replicate animal tissue (such as a meat replica) but without using components derived from animals.

A. Challenged Patents

a. '096 Patent (EX1156)

35. I understand that the '096 patent purports to claim priority to PCT Application No. PCT/US2014/011347 filed July 17, 2014, U.S. Application No. 13/941,211 filed July 12, 2013, a provisional application (U.S. Provisional No. 61/908,634) filed November 25, 2013, and a provisional application (U.S. Provisional No. 61/751,816 filed January 11, 2013. *See* EX1156('096 patent), 1-2, 14 (patent cover page, related U.S. application data). I understand that, in these Proceedings, Motif argues that the Challenged Claims of the '096 patent are not entitled to claim priority to the January 11, 2013 provisional filing date.

b. '241 Patent (EX1159)

36. I understand that the '241 patent purports to claim priority to U.S. Application No. 14/797,006 filed July 10, 2015, a provisional application (U.S.

Provisional No. 61/908,634) filed November 25, 2013, and a provisional application (U.S. Provisional No. 61/751,816 filed January 11, 2013. *See* EX1159('241 patent), 1-2, 18 (patent cover page, related U.S. application data). I understand that, in these Proceedings, Motif argues that the Challenged Claims of the '096 patent are not entitled to claim priority to the January 11, 2013 provisional filing date.

c. '306 Patent (EX1001)

37. I understand that the '306 patent purports to claim priority to PCT Application No. PCT/US2014/011361 filed January 13, 2014, U.S. Application No. 13/941,211 filed July 12, 2013, a provisional application (U.S. Provisional No. 61/908,634) filed November 25, 2013, and a provisional application (U.S. Provisional No. 61/751,816 filed January 11, 2013. *See* EX1001('306 patent), 1-2, 18 (patent cover page, related U.S. application data).

d. '250 Patent (EX1158)

38. I understand that the '250 patent purports to claim priority to PCT Application No. PCT/US2014/011361 filed January 13, 2014, U.S. Application No. 13/941,211 filed July 12, 2013, a provisional application (U.S. Provisional No. 61/908,634) filed November 25, 2013, and a provisional application (U.S. Provisional No. 61/751,816 filed January 11, 2013. *See* EX1158('250 patent), 1-2, 22 (patent cover page, related U.S. application data).

B. Person of Ordinary Skill in the Art (POSITA)

39. The Challenged Patents are directed to the art of food science and recombinant protein expression. A POSITA would have (i) a Bachelor of Science degree in food sciences, biology, chemistry, microbiology, or a related discipline, and (ii) a Master's degree or Ph.D. in food science or at least three years of experience working as a food scientist. A POSITA could also be part of a team of food scientists, including flavor chemists.

C. GMOs in the Early 2000s

40. Since its advent in the 1980s, recombinant DNA technology has enabled the production of proteins and other macromolecules for use in a variety of applications—from human therapeutics to food ingredients. For example, genetic engineering of food was a well-understood technology by the early 2000s. Around that time, food scientists were increasingly looking to recombinant technology. One example of the intersection of these two disciplines are Genetically Modified Organisms ("GMOs"), which are produced using scientific methods that include recombinant DNA technology. Recombinant DNA is used to create organisms whose genomes have been precisely altered at the molecular level by the inclusion of genes from unrelated species of organisms that code for desirable traits.

41. GMOs began entering grocery stores in the 1990s—modified with genes to prolong shelf life. EX1084(Fellows), 231. For example, in 1994, a tomato

was modified to "reduce the level of polygalacturonase and hence reduce softening" thereby "increas[ing] the shelf-life." *Id*. By the early 2000s, GMOs became increasingly "[c]ommercially produced," including modifying crops with genes that make them "resistant to herbicides or insects." *Id.*

42. In 2004, the share of crops in global trade that had been genetically modified was estimated to be "90% for soybeans, 80% for maize, 44% for cottonseed and 73% for rapeseed." *Id.* By 2006, about "60% of all … processed foods" in the U.S. contained a GMO ingredient. *Id.*, 234.

43. Practical applications of genetically modified foods include modifications to mask undesirable taste, to improve nutritional value, or to produce processed foods that target a health concern. *Id.*, 241.

44. Along with GMOs, considerable scientific advances were made in the production of ingredients, either to expand the sources of existing ingredients or to create new ingredients. The most notable example is the microbial production of chymosin, an enzyme used in cheese making. Traditionally extracted from the calf's stomachs, today recombinant chymosin dominates in cheese production.

D. <u>Crane's Application to Food Science</u>

45. In light of the advanced state of the art of recombinant technology and its application to the food science industry, a POSITA for the Challenged Patents

would naturally look to references such as Crane to produce heme-binding proteins such as hemoglobin or leghemoglobin.

46. In the 1980s, based upon the successful use of recombinant proteins in clinical settings, including (for example) insulin and human growth hormone for human use, the food industry's attention was turned to the production of recombinant proteins for use as food ingredients. A pioneering example of a food ingredient produced using recombinant techniques was the manufacture of chymosin (rennet) in the microbial system of *Escherichia coli*. Like other expression systems (e.g., *P. pastoris*), *E. coli* can be used as a host to produce proteins for human consumption—which Crane expressly contemplates.

47. Chymosin is an enzyme used in cheese production and is responsible for the formation of curd. Historically, milk was transported in containers made from a calf's stomach. Over time, because of the presence of chymosin, the liquid milk would coagulate, acquire a pleasant acidic taste (fermentation by native microorganisms), and could last longer. Upon identifying the active enzyme ingredient in calf's stomach, chymosin was subsequently produced and made available to cheese makers. Up until recombinant systems were developed in the 1980's, chymosin was derived from the veal calf stomach. In the mid-1980's recombinant systems to produce chymosin were developed and put into routine use.

This represented a more stable means of producing chymosin as it was no longer dependent upon the supply of veal calves.

48. That *E. coli* could be used to produce food ingredients like chymosin was not unexpected. The production of chymosin in *E. coli* was not technically complicated and followed the same basic process as the production and scale of insulin and other proteins. Specifications on purity and consistency of the end-product are part of any good manufacturing process and would be within the ordinary skill of a POSITA at the time of the Crane invention.

49. As another example of recombinant technology used for such purposes, during the 1980s and 1990s, my laboratory used *E. coli* to produce a whey protein that could be used for human consumption. EX1138, Jamieson et al., *Cloning and nucleotide sequence of the bovine β-lactoglobulin gene*, Gene 61: 85-88 (1987); EX1137, Batt et al., *Expression of recombinant bovine β-lactoglobulin in* Escherichia coli, Agr. Biol. Chem. 54, 949-955 (1990).

50. Given the safety of recombinant proteins for use in food, a POSITA would understand that the recombinant proteins produced via Crane's methods could be suitable for use in food products. Crane teaches methods of producing "proteins [that] are completely functional and are more suitable for … commercial applications," which include clinical applications. EX1014(Crane), [0024]. Because Crane produces proteins that are suitable for clinical applications, a

POSITA would understand that Crane could be used for food applications. Generally speaking, the bar for purity, consistency and safety in clinical applications is higher than in food applications. Thus, a POSITA would understand the fact that since Crane discloses methods and products for clinical applications they are suitable for food applications as well.

51. A POSITA would be motivated to utilize the Crane reference to produce recombinant heme-binding proteins for use in a food product, such as a meat replica, where there was a desire to avoid animal-derived proteins. For example, Crane provides "a straightforward and inexpensive method for high fidelity incorporation of heme into recombinantly overexpressed heme proteins." EX1014(Crane), [0014]. In light of Crane's disclosure of techniques for creating fully-iron-incorporated heme proteins and a POSITA's general knowledge regarding the field of genetic engineering, a POSITA would be able to use Crane's disclosure to create "homogeneous commercial heme-binding proteins with high activity." *Id.*

52. A POSITA would reasonably expect to obtain high levels of recombinant heme-binding proteins, such as leghemoglobin, by following the disclosure of Crane. *Id.*, [0021]. As noted, the field of recombinant DNA expression was well developed by 2010. As part of its disclosure of systems and methods for recombinant expression, for example, Crane teaches the production of heme-

containing proteins through expression systems with "strong promoters to obtain a high level of … expression." *Id*., [0040].

53. Accordingly, Crane should be considered analogous art because a POSITA would understand that it is from the same field of endeavor as the claimed subject matter, even if the ultimate application differs. Additionally, a POSITA would naturally look to Crane and recombinant arts to create ingredients for use in meat replicas because it is reasonably pertinent to the problem faced by the named inventors, even if it is not in the same field of endeavor as the claimed invention.

VII. CONCLUSION

54. In signing this Declaration, I recognize that the Declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

55. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on the information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dr. Carl Batt, Ph.D.

12-3-22

Date