AUSTRALIA

Patents Act 1990 (Cth)

In the Matter of Australian Patent Application No. 2002322233 in the name of **Neptune Technologies & Bioressources Inc.**
– and –
Opposition thereto by **Aker Biomarine ASA** (Opp 1)

DECLARATION

I, Richard Charles Oppenheim, of 67 Gladstone St., Kew, Victoria 3101, Australia, do solemnly and sincerely declare the following.

1. I have been provided with a copy of the Federal Court Practice Direction – Guidelines for Expert Witnesses in proceedings in the Federal Court of Australia, and have read and understood these guidelines. Now produced to me and marked "**RCO-1**" is a copy of these guidelines.

2. I understand that this information is relevant to a controversy between Aker Biomarine ASA and Neptune Bioressources Inc. regarding patent claims.

3. I have no direct relationship with Aker Biomarine ASA or Neptune Bioressources Inc. and I am unaware of whatever patents may be involved. I have not been provided with copies of any patent or patent application in relation to my making this declaration and I have not otherwise read or reviewed any patents or applications in relation to this controversy.

4. I am being compensated for my time taken in the preparation of this declaration.

5. I have been asked by Pizzeys Patent and Trade Mark Attorneys to provide information in relation to the knowledge and state of the art in the commercial formulation and manufacture of complementary medicines based upon or employing dietary oils such as fish oil and krill oil as at 27 July 2001 ("the Relevant Date").

6. Unless I state otherwise, I make the statements below based on my personal experience and knowledge of the related science and art, and my knowledge of what others in my profession would have known as at the Relevant Date.

Knowledge and Experience

7. My current Curriculum Vitae is attached and marked as "**RCO-2**".

8. My present position is as Principal of "Dr Richard C Oppenheim". As the Principal of this company, I work with the therapeutic goods and food industries in Australasia, within the PacRim area, in Europe and in North America. Clients have ranged over companies manufacturing and marketing Prescription and OTC products, Complementary Medicines and Dietary Supplements as well as Devices and foods.

9. I also currently serve on the Advisory Committee for Complementary Medicines (ACCM). I have expertise and skill in the manufacture of medicines, including complementary medicines, and I provide advice to the TGA through my role on ACCM.

10. ACCM provides scientific and policy advice to the Therapeutic Goods Administration (TGA). This advice relates to the supply, use, safety and quality of products and, where appropriate, efficacy relating to the claims made for products.

11. I have been involved in matters regarding the regulatory specifications for oils as complementary medicines or dietary supplements, including fish oils and krill oil. The regulatory specifications administered by the TGA include raw material specifications, *i.e.* the way the material such as krill oil is described so as to distinguish it from conventional fish oil or vegetable oil. The TGA acts, and the

ACCM advises, in a regulatory function ensuring the safety and quality of products and is in no way related to intellectual property or patents.

12. In 2001-2002 I was an employee of R P Scherer Australia (a part of the world wide Scherer Corporation which became part of Cardinal Health Inc. in 1998, and which became Cardinal Health Australia in 2002). The company at that time was a major contract developer of formulations and manufacturer of products incorporating complementary medicine substances. I held the position of Pacific Regional Technical Director of the company. My roles with the company are particularly described in my *Curriculum Vitae*.

13. From 1998 to 2003, I was the Pacific Regional Technical Director for R P Scherer Australia, and based in Melbourne. I reported to a vice president and the Australian general manager. I had responsibility within Australia for the technical department and regulatory affairs in Australia. I oversaw the development of specification documents and I was responsible for overall good manufacturing practice in the facility for making medicines, including complementary medicines. My technical focus, and my employer's prime focus at the time was in complementary medicines, dietary supplements, and "health foods" in Australia and the Pacific Region. Scherer also had facilities in Japan and Korea, and I had responsibility for technical matters for those facilities as well on technical and regulatory operational management.

Australian Complementary Medicines Industry in July 2001

14. In 2001 the state of the industry was such that the majority of complementary medicines being made in Australia were being made by contract manufacturers, including R P Scherer (Cardinal Health), Pan Pharmaceuticals, and smaller companies such as Lipa Pharmaceuticals, and a whole range of much smaller contract manufacturers. At that time, there were a small number of soft capsule contract manufacturers in the Australia and Pacific Region. R P Scherer would have been one of the biggest.

15. Contract manufacturers would either provide the finished product (e.g. bottled tablets or capsules) to the marketer, or they might provide manufactured bulk product, which might then be re-packaged for sale. Nutraceuticals and complementary medicines were being manufactured in this fashion in Australia in 2001. Indeed, that was the primary business of R P Scherer.

16. The role of contract manufacturers in providing these products would typically begin with contract manufacturers taking "known actives" (known active ingredients approved for specific uses by the TGA) and reformulating them in new combinations as new products for the market. These were formulations of new actives that had received approval, *e.g.* fish oil with vitamin E added, and the like. All the actives in these sorts of products would have already and typically been pre-approved by the TGA for the contemplated uses.

Patents in the Australian Nutraceutical and Complementary Medicine Industry in 2001

17. I have been asked about the extent to which someone involved in the processes of formulating and bringing to market complementary medicines or nutraceuticals in Australia would have been aware of patents.

18. In answer, someone in my position with a contract manufacturer at the time would have definitely been aware of patents to actives and their formulations. For example, a role of mine at R P Scherer at that time was to maintain their patent position and I was aware of the patent landscape for the products made by them. This was essential to a successful business as a contract manufacturer, which were the primary suppliers to the market of nutraceuticals and complementary medicines at the time. One of my functions was to review patent landscapes and freedom to operate issues so as to understand what products could be made or reformulated in Australia in relation to IP rights. This was typical and critical for successful development of any new product manufacture or distribution in Australia.

19. For example, if a customer proposed a product as a new combination of actives, for example fish oil with vitamin C added, that description would come to my

department. An assessment of the patent landscape for such a product would occur very early in the process. When we received a proposal we would first see if there were patent problems or barriers in relation to the actives proposed.

20. Then we would assess if the contemplated product would be technically sensible, considering issues such as the potential adverse chemical reactions that might occur in the product, then advise the customer as how to we proposed to formulate the product.

21. If the formulation appeared feasible, we would get a costing of the formulation. The customer would ultimately take an application to ARTG to get approval for marketing the new formulation, once it passed these hurdles.

22. The costs associated with this process would depend on how much work had to be done to assess and modify the product or formulation. For example, stability is a primary concern, and you might have to spend tens of thousands of dollars to assess and find the appropriately stable formulation. The development of the manufacturing steps for such a formulation or capsule might cost as much as $20,000 or more. You certainly would not want to take these steps if the earlier assessments were at all problematic, or if the actives or formulations were protected by patents. So, knowledge of the relevant patents for the products was critical early in product development. If the patent landscape were not clear, then the project would be unlikely to proceed.

Oils as Known Actives in July 2001

23. Among the known actives in the industry as early as July 2001 were various oils, fatty acids, and phospholipids. In particular, fish oils were an active ingredient attracting a great deal of interest by July 2001. There was an early interest in concentrated fish oils.

24. Krill oil was also known to the industry at the time particularly because it was a difficult active ingredient to deal with because of its high phospholipid content. Soft capsules made with krill oil as the fill material would suffer from a problem of capsules leaking. Normal fish oil wouldn't have that problem because it wouldn't

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