Section 2; Isolation and Modification of a Togavirus strain

Amended claims to the characteristics of the altered state of an isolated virus from body fluids and modified to a useful togavirus strain free of primate proteins and useful in making vaccines, were held allowable under Section 2. Rejection modified.

This decision deals with Applicant's request for review by the Commissioner of Patents of the Final Action on application 400,069 (Class 167-41) filed March 31, 1982. Entitled NON-A, NON-B HEPATITIS ASSAY AND VACCINE, it is assigned to Connaught Laboratories Ltd. The inventors are P.L. Coursaget, P. Maupas (deceased). The Examiner in charge issued a Final Action on June 22, 1984, refusing to allow the application. A Hearing was held on May 18, 1988, at which the Patent Agent, Mr. M.I. Stewart, represented the Applicant. On May 26, 1988, Mr. Stewart submitted a set of amended claims.

The application relates to a togavirus strain particle that has been discovered in body fluids of Non-A, Non-B (NANB) hepatitis patients, and that has been rendered noninfective for tissue culture by exposure to ether or upon heating at about 25°C in aqueous suspension. The particle may be replicated in vitro by culturing, recovered by decanting, and purified.

In rejecting claims 1 to 6, and 10 to 15, the Examiner said, in part, as follows:

> . . .
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> The refusal of claims 1 to 6 and 10 to 15 is maintained. Claims 7 to 9 and 16 to 23 are allowable. The rejected claims define subject matter that is outside the definition of invention as given in Section 2 of the Patent Act and outside the criteria set out in the decision of Abitibi published on July 6, 1982. Applicant's product has been isolated from nature. Therefore it is not new and inventive.
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> In applicant's last response and in the disclosure, it is mentioned that the product claimed has been isolated and purified from "body fluids", for example "urine" and "serum". See letter of May 3, 1984, first paragraph and in the disclosure on pages 3/4 lines 10-18.

> Therefore the product does not comply with the criteria of Abitibi and Section 2 of the Patent Act. "The organisms, to be claimed, should not of course have existed previously in nature, for in that event the "inventor" did not create it, and his "invention" is old. And it must be sufficiently different from known species that it can be said that its creation involved the necessary element of inventive ingenuity". (Abitibi last paragraph).
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> . . .

The Applicant contended that the rejected claims were allowable, arguing in part, as follows:

> Non-A non-B (NANB) hepatitis is defined as clinical hepatitis which cannot be attributed to infection by cytomegalovirus, Epstein-Barr virus or hepatitis A or B. NANB hepatitis represents up to 90% of the post-transfusion hepatitis cases and the risk of contracting NANB hepatitis is very high. NANB hepatitis has been found to be associated with a variety of virus-like particles. What the inventors have found is a particular previously-unknown and previously-unidentified virus particle which is an etiological agent for NANB hepatitis. By isolating and purifying the particle, there is obtained an agent useful for making vaccines against NANB hepatitis and conducting immunoassays for detecting NANB hepatitis.
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> The applicant does not deny that the invention defined in the rejected claims is <u>based on</u> materials found in the body fluids of humans but such materials are <u>not</u> claimed. Claim 1 defines a togavirus strain which is <u>isolated from</u> the body fluids of a patient diagnosed to have NANB hepatitis, and <u>purified</u>.
>
> Claim 1 does <u>not</u> define a product found in nature but rather an isolated and purified form of a viral particle, which, it is submitted, <u>in this form</u> is a new substance. What the inventors had to do was to screen samples of body fluids from patients apparently suffering from NANB hepatitis, identify an apparently causative virus, and only then isolate and purify the viral particle for further analysis and characterization.
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> Others of the rejected claims also clearly do not define a product as found in nature....
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> . . .
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> Contrary to (the Examiner's) position, it is submitted that the Abitibi case actually supports the applicant's position that the rejected claims define patentable subject matter. It is clearly stated therein (see page 89 of the decision as it appears in 62 C.P.R. (2nd) 81):
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> > "...this decision [i.e. a finding that lifeforms are patentable] will extend to <u>all</u> micro-organisms...<u>viruses</u>..." (Emphasis added).
>
> . . .

> The applicant does not deny that the product has been isolated from body fluids but does deny that this means that the isolated and purified product defined in claim 1 and further modified and processed forms thereof defined in claims 2 to 6 and 10 to 15 is not new and inventive subject matter. The applicant is not claiming the product as it appears in nature but rather a processed form thereof. Further, whether or not the material is "new and inventive" has nothing to do with what constitutes subject matter outside the definition of "invention" in Section 2 of the Patent Act. The Abitibi case clearly states that viruses are per se patentable subject matter, as noted above, so that the Examiner's rejection is without foundation.
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> . . .
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> As to whether or not the products defined in the rejected claims are new and inventive, it is submitted that the products meet the legal requirements in this regard. The hitherto-unknown viral particle defined in claim 1 has been identified in the body fluids of NANB hepatitis patients, the product has been isolated and purified and the viral particle characterized. The viral particle as defined in claim 1 does not exist in nature, is a new and useful product and may be manufactured in significant quantities by cultivation, as described in the specification. It is submitted that these characteristics meet all the criteria of the quoted portion of the Abitibi decision.

The issue before the Board is whether or not claims 1 to 6, and 10 to 15 define subject matter that is patentable within Section 2 of the Patent Act. Amended claim 1 reads:

> A togavirus strain isolated from the body fluids of a patient diagnosed to be suffering from non-A, non-B hepatitis and purified, said purified strain being substantially free of primate proteins and having identifying characteristics of ATCC accession nos. VR-2011, VR-2012, VR-2013 or VR-2014, said togavirus strain comprising a particle of diameter of about 50 to 60 nm.

Mr. Stewart opened the Hearing by proposing that the rejected claims be considered in light of amendments he suggested be included to identify the purified strain in claim 1 line 3 as "being substantially free of primate proteins" and as having "identifying characteristics" of the accession numbers stated on lines 5 and 6. These modifications are set forth in the amended claim above he submitted on May 26, 1988, after the Hearing.

Mr. Stewart explains that the Applicant's invention involves the isolation of a togavirus strain from body fluids, notably from urine, of NANB hepatitis patients. By this isolation, he states, the Applicant has succeeded in

obtaining the causative agent in hepatitis that was not previously known to exist. He notes that a further modification, namely purification, was needed to obtain a substance useful to make vaccines, or testing materials for assays. He adds that such a modified particle is not found in the body fluids, as was the causative agent. He points out that if the unpurified togavirus were injected into a patient, most likely the patient would become infected, whereas injection of a purified togavirus would not so affect a patient. Due to the purification step, he says that the hand of man was present to change the isolated virus into something useful.

The examiner contends that for a substance like the Applicant's virus to be a patentable subject matter, it would have to be man made. He rules out that the Applicant's transformation of a virus falls within a patentable art area. He believes that neither isolating, nor merely purifying, a virus alters it from the state in which it was found in the body fluids.

Mr. Stewart notes the discussion and determination relating to what is a chemical reaction, as given in Laboratoire Pentagone Limitée v. Parke Davis & Co. (1968) S.C.R. page 307. There, he points out, it was concluded that the processes of extraction described in the patent should be regarded as chemical processes in the usual sense of the term "chemical process". Mr. Stewart regards the solvent extraction under review in Laboratoire Pentagone as being by the hand of man, just as he regards the purification process used by the Applicant is something attributable to the hand of man. He stresses that it is the purified state of the togavirus particle that makes it usable, whereas without purification the togavirus may not be used in the manner described by the Applicant.

Mr. Stewart refers to Re Application of Abitibi Co. 62 C.P.R. (2d) 81, a Commissioner's Decision dated March 18, 1982, saying it supports the patentability of his client's claims. He argues the Decision extends to "micro-organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa", such as may be produced en masse, as chemical compounds are formed (page 89).

In summary, the Examiner suggests that the purified togavirus of the amended claims is nothing more than the virus that exists in nature, and which may be readily available from the body fluids. The Agent counters by saying the application describes, and by pointing out in his arguments, that the togavirus was not known to exist by itself in nature, but had to be isolated, from the body fluids, and then purified to a certain limit to meet the identifying characteristics of American Type Culture Collection accession numbers.

We are persuaded that the togavirus defined in the amended claims did not exist in nature. We think the Applicant has isolated a particle resembling a togavirus strain from a body fluid containing many kinds of elements. He says the particle was previously unknown, and after isolation, the particle was altered by purification. From the Applicant's arguments, he says the purified strain would not affect a patient, whereas the isolated only virus would.

In the Abitiți decision we find the following passage to be significant to the issue before us:

> The organism, to be claimed, should not of course have existed previously in nature, for in that event the "inventor" did not create it, and his "invention" is old. It must also be useful, in the sense that it carries out some useful known objective, such as separating oil from sand, producing antibiotics or the like. It cannot be a mere laboratory curiosity whose only possible claim to utility is as a starting material for further research. And it must be sufficiently different from known species that it can be said that its creation involved the necessary element of inventive ingenuity.

In view of the above reasoning in Abitibi, and the nature of and utility described for the purified togavirus particle, we are satisfied the Applicant's amended claims meet the tests outlined by Abitibi.

We recommend that the amended claims be accepted.

M.G. Brown
Acting Chairman
Patent Appeal Board

S.D. Kot
Member

I have reviewed the findings and the recommendation of the Patent Appeal Board. Accordingly, I accept the amended claims, and I remand the application for examination consistent with the recommendation.

J.H.A. Gariépy
Commissioner of Patents

Dated this 20th day of September 1988
Hull, Quebec

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