COMMISSIONER'S DECISION

INSUFFICIENT DISCLOSURE S.36(1): Undisclosed Subject Matter Claimed.

The decision affirmed that some claims are too wide in covering whole classes of substances which were obviously untried and untested. In addition, while claims for benzothiadiazines (claimed in other patents by the applicant and others) mixed with hypotensive agents may be inventive, there was no disclosure of such invention as required by S.36(1). Other objections that the claims were not patentably different from subject matter lost in conflict, and that there is lack of invention, were reversed. The disclosure does not reveal any unexpected synergism, nor does it give adequate details of the operation, use or effect of such a composition.

FINAL ACTION: Affirmed in-part.

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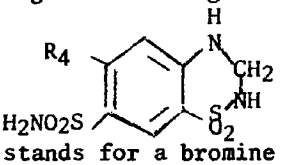
On March 9, 1960, CIBA Limited filed an application for patent, serial no. 794,095, Class 167 - 213, for 3:4-Dehydro-1:2:4-Benzo-thiadiazine-1:1-Dioxides and a Process for Their Manufacture. The inventors were George De Stevens and Lincoln H. Werner, assignors to Ciba. After numerous actions the examiner rejected the application on January 8, 1973. The applicant subsequently requested a review of the rejection by the Commissioner of Patents, and a Hearing before the Patent Appeal Board. The Hearing took place on May 8, 1974, at which time Mr. George Seaby represented the applicant.

The application contains 240 claims, of which 180 are for a process of "combining" certain benzothiadiazines with a hypotensive agent. The remaining 60 claims are for the mixtures so produced. The product claims are made dependent upon the process claims. Though claims 22 and 188 will be adequate to illustrate the nature of the invention, the chemical complexities of which need not concern us, claim 1 is also reproduced to indicate the breadth of the invention claimed. It would be no exaggeration to say that tens of thousands of compounds are encompassed by the claims.

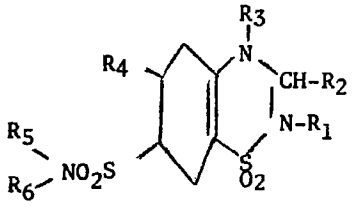
Cl. 22 Process for the manufacture of a pharmaceutical preparation consisting of combining a compound of the formula



in which R_4 stands for a bromine or fluorine atom, a methoxy or methyl group, or an alkali metal salt thereof together with a hypotensive agent.

Cl. 188 Pharmaceutical preparations whenever prepared or produced by the process of any one of claims 22, 23 and 24, or by any process which is an obvious equivalent thereof.

Cl. 1 Process for the manufacture of a pharmaceutical preparation consisting of combining a compound of the formula



in which each of the groups R_1, R_3, R_5 and R_6 is hydrogen, an alkyl or an acyl group, R_2 represents hydrogen, or an aliphatic hydrocarbon radical, a cycloaliphatic radical, a cycloaliphatic-alkyl radical, an aryl radical, an araliphatic radical, a heterocyclic or heterocyclic-alkyl radical, the heterocyclic radical of these latter being monocyclic and containing one oxygen, nitrogen or sulfur atom in the ring, all these radicals being either unsubstituted or substituted by halogen atoms, free, esterified or etherified hydroxyl or mercapto groups, nitro, amino, acylamino, monoalkyl-, dialkyl- or N,N-alkylene-amino groups, whose alkylene radical may be interrupted by a hetero-atom, carboxyl groups, sulfamyl or alkyl groups, and R_4 stands for an unsubstituted or halogen-substituted alkyl radical, an esterified or etherified hydroxyl group or a halogen atom, with the proviso, that whenever R_4 is chloro, at least one of the groups R_1, R_2, R_3, R_5 and R_6 stands for one of the above organic radicals, or a salt thereof, together with a hypotensive agent.

The prior prosecution of this application has been both long and involved. Because of its complexity, it will be more appropriate to summarize the objections made, rather than to quote directly from the actions and responses themselves:

1. The admixtures claimed are not inventively different or patentably distinguishable from subject matter the applicant lost in conflict proceedings involving other applications of the applicant.

2. There is no invention in mixing the new compounds, which have hypotensive properties, with other known hypotensive compounds. Such admixtures would be obvious to one skilled in the art.

3. There has not been any proper disclosure of an invention.

4. The admixtures claimed are not patentably different from claims made elsewhere by the applicant to the new compounds themselves. In utilizing this argument the examiner relied extensively upon the decision of the Supreme Court of Canada in Commissioner of Patents v. Farbwerke Hoechst (1964) S.C.R. 49, which, he contends, stand for the proposition that if a chemical compound has already been patented, claims to that compound in admixture with other ingredients are not patentable where no additional invention subsists in and has been disclosed for that admixture.

5. The claims are too broad, covering a class of indefinite size, so large that an assertion as to the properties and usefulness of the substances are unfounded and unwarranted.

6. Section 41 is applicable, and requires that the products be claimed by way of the chemical process by which they were manufactured, rather than by the step of admixing them with the hypertensive agents.

There are many similarities between the rejection made in this case and that in the case of copending application 081,556 of the same inventors and applicant, both of which were heard by the Board at the same time. In a decision dated August 2, 1974, the Commissioner sustained the rejection of application 081556. There are however, some differences between the rejections. In the present application, for example, process-type claims are present, and the composition claims are made dependent upon the process-type claims, so that in form at least Section 41 of the Patent

Act has been complied with. In addition, of course, the scope of the claims is much broader, since R_2 is the chloromethyl radical in 081556.

From the claims quoted above, it will be apparent that the invention of the applicant is a composition consisting of particular benzothiadiazines mixed with a hypotensive agent. The precise chemical structure of the benzothiadiazine is immaterial to what must be decided, and the compounds will hereinafter be referred to as "benzothiadiazine." The "process" merely calls for "combining" (or mixing) the benzothiadiazine" with a hypotensive agent. No particular procedural steps are disclosed or claimed for preparing the composition, and all that is involved is the common expedient of mixing two ingredients together. Divorced from any invention in the product, the "process" would be unpatentable. As for the benzothiadiazines, they possess duretic and other properties which make them useful medicinally.

First to be considered is the objection that subject matter in the claims was lost by CIBA during conflict proceedings, and now appears in Canadian Patent 681760 to Bristol-Myers and C.P. 719693 to Abbot Laboratories. We have found that the broad claims of the application encompass and some of the specific compositions do in fact appear in those patents. As one example, claims 30, 89 and 190 of this application cover the same subject matter as C.P. 681760 (Bristol-Myers). Both of the patents had been involved in conflict proceedings with application 771510 (now patent 697915) filed by George de Stevens and Lincoln H. Werner and assigned to CIBA. They were also in conflict with another CIBA application, now patent 696,976, which stands in the name of another inventor, E.A. Jack. In his response the applicant argues firstly that since this particular application was not part of the conflict,

the outcome of the conflict has no bearing on it; and secondly that his rights to the matter now being claimed were not settled by the conflict. With the first argument we would disagree, but we are persuaded by the second. When it has been determined that an inventor is not the first inventor of subject matter as the result of conflict proceedings involving one of his applications, he should not be able to claim it in another of his applications. Section 28(1)(a) would preclude this. In this instance, however, we have not been able to ascertain from the evidence with certainty that the conflict resolved priority against the applicant on the subject matter claimed here. On this point we find the applicants submissions persuasive, and consequently are satisfied this objection should not be pursued further.

Similarly we do not think there is anything to be gained in maintaining that the admixtures claimed are not in fact inventive. Evidence to that effect was introduced with the amendment of September 8, 1969. (This, it may be noted, is more than nine years after the application was filed). Similarly the issuance of Canadian patents 681760, 696976, 697915 and 719693 (referred to previously) testify to that fact that mixtures of the benzothiadiazine with hypertensive agents amount to invention. The applicants submission provides many instances of products on the market based upon the invention, and adequate evidence as to its patentability.

It is when we consider the adequacy of the disclosure, however, that we believe the application must fail. All thirty-one pages of the disclosure and all the examples describe the benzothiadiazines, a process for preparing them by chemical reduction of a C=N double bond and

subsequent acylation, and tabletting with binders. The sole reference to using them with hypotensive agents appears in the last sentence of the paragraph bridging pages 6 and 7, which is quoted below (underlining added):

> The new compounds may be used as medicaments in the form of pharmaceutical preparations which contain the compounds in admixture with a pharmaceutical organic or inorganic, solid or liquid carrier suitable for enteral, e.g. oral, or parenteral administration. For making up the preparations there may be employed substances which do not react with the new compounds, such as water, gelatine, lactose, starches, magnesium stearate, talc, vegetable oils, benzyl alcohols, gums, polyalkylene glycols, petroleum jelly, cholesterol or any other known carrier for medicaments. The pharmaceutical preparations may be in solid form, for example, as tablets, dragees or capsules, or in liquid form as solutions, suspensions or emulsions. If desired, they may be sterilized and/or contain auxiliary substances, such as preserving agents, stabilisers, wetting or emulsifying agents, salts for varying and osmotic pressure or buffers. They may also contain other therapeutically useful substances, for example hypotensive agents, such as Rauwolfia or Veratrum alkaloids, e.g. reserpine, rescinnamine, deserpidine, germine or protoveratrine, synthetic hypotensive agents, e.g. hydralazine, or ganglionic blockers, such as chlorisondamine.

While it may be possible for a single sentence to provide sufficient disclosure to warrant claims to some inventions, we do not think that can be the case here. There is no indication in it of any unexpected synergism, or adequate details about the operation, use of effect of the invention. Clearly Section 36(1) is not satisfied. In Radio Corporation of America v. Raytheon Manufacturing (1956-1960) Ex. C.R. 98 at 108, it was stated, for example, that:

> It is a cardinal principle of patent law that an inventor may not validly claim what he has not described. In the patent law jargon it is said that the disclosures of the specification must support the claims. If they do not, the claims are invalid. Moreover, there is a statutory duty of disclosure and description that must be complied with if a claim for an invention is to stand. Section 35 of the Patent Act, 1935, provides, in part:

"35. (1) The applicant shall in the specification correctly and fully describe the invention and its operation or use as contemplated by the inventor, and set forth clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most closely connected, to make, construct, compound or use it. In the case of a machine he shall explain the principle thereof and the best mode in which he has contemplated the application of that principle. In the case of a process he shall explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions. He shall particularly indicate and distinctly claim the part, improvement or combination which he claims as his invention.

(2) The specification shall end with a claim or claims stating distinctly and in explicit terms the things or combinations which the applicant regards as new and in which he claims an exclusive property or privilege."

In Minerals Separation North American Corporation v. Noranda Mines Limited (1947) Ex. C.R. 306 I had occasion to consider the duties of disclosure required of an inventor in consideratio.. of the grant of a valid monopoly in respect of his invention. At page 316, I said:

"Two things must be described in the disclosures of a specification, one being the invention, and the other the operation or use of the invention as contemplated by the inventor, and with respect to each the description must be correct and full. The purpose underlying this requirement is that when the period of monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application. The description must be correct; this means that it must be both clear and accurate. It must be free from avoidable obscurity or ambiguity and be as simple and distinct as the difficulty of description permits. It must not contain erroneous or misleading statements calculated to deceive or mislead the persons to whom the specification is addressed and render it difficult for them without trial and experiment to comprehend in what manner the invention is to be performed. It must not, for example, direct the use of alternative methods of putting it into effect if only one is practicable, even if persons skilled in the art would be likely to choose the practical method.

The description of the invention must also be full; this means that its ambit must be defined, for nothing that has not been described may be validly claimed. The description must also give all information that is necessary for successful operation or use of the invention, without leaving such result to the chance of successful experiment, and if warnings are required in order to avert failure such warnings must be given. Moreover, the invent

> must act uberrima fide and give all information known to him that will enable the invention to be carried out to ts best effect as contemplated by him."
>
> and I cited the cases from which this statement was abstracted. The statutory requirement then in effect was section 14 of The Patent Act, Statutes of Canada, 1923, Chapter 23, and I made the statement that it merely puts the requirements of the law, as laid down in the cases, into statutory form. While my judgment in the Minerals Separation case (supra) was reversed, the statement I have cited has not been challenged. And it is applicable in a case to which section 35 of The Patent Act, 1935, applies: vide Di Fiore v. Tardi, (1952) Ex. C.R. 149 at 154. The onus of disclosure that the section places on an inventor is a heavy and exacting one. (underlining added)

The same theme was developed in French's Complex Ore v Electrolytic Zinc 1930 S.C.R. 462, Smith Incubator v. Sealing 1937 S.C.R. 251, Minerals Separation v. Noranda Mines 1947 Ex. C.R. 306 at 316, Gilbert v. Sandoz (1971) 64 C.P.R. 7 at 42-45, and Rhone-Poulenc and CIBA v. Gilbert 1966 Ex. C.R.59 & 1967 S.C.R. 45.

As for the evidence now presented that invention is in fact present, we would refer to the statement of the President of the Exchequer Court in Riddell v Patrick Harrison 1956-60 Ex. C.R. 213 at 225:

> ...what has to be considered in a patent case is the invention as described in the specification and defined in the claims rather than that described in the evidence."

That it would have been easily possible to provide a full disclosure of the invention when this application was filed is demonstrated by the disclosures of Canadian patents 719693 and 681760 (cf supra), or even by CIBA's own patents 696976 and 697915. The contract between those disclosures and that in this application accentuates the inadequacies in the latter.

We have already indicated the scope of the broad claims illustrated previously by claim 1. There is more than adequate precedent in Boehringer Sohn v. Bell Craig 1962 Ex. C.R. 201 and 1962 S.C.R. 410; Farbwerke Hoechst v. Commissioner of Patents 1966 Ex. C.R. 91 and 1966 S.C.R. 606; Burton Parsons v. Hewlett-Packard 7 C.P.R. (2d) 1973 198

and 10 C.P.R. (2d) 126; Rhône-Poulenc & CIBA v. Gilbert 1966 Ex. C.R. 59 and 1967 S.C.R. 45 and Hoechst v Gilbert 1965 Ex.C.R. 710 1966 S.C.R. 189 to warrant rejecting the broad claims, such as claims 1-44 inclusive and 181-195 inclusive.

As was said in the latter case (in the Exchequer Court):

> ... the proposition that all or substantially all of the limitless number of substances which could be produced by these processes as defined have value as oral antidiabetic medicines, when it is apparent from the mere size of the class that most of its members could never have been made or tested by anyone, is so preposterous as to require little in the way of evidence to dispel any presumption of its truth. Presumed or not the proposition shocks ones credulity.

We see little value in developing the objection based on Section 41. That issue is beclouded in this instance by such questions as what invention has been disclosed, what invention has actually been made, the grant of the four patents mentioned previously which were not put under Section 41, the form of the claims in this application, and whether the term "combining" properly defines a process. Since we believe the patentability of the claims has been fully decided by Section 36 and the inadequacies of the disclosure, we recommend that objections based on Section 41 should not form part of the reasons for a refusal by the Commissioner.

We note that the claims overlap patents already granted to CIBA, and also in some instances to the inventors of this application, such as Canadian Patents 697915, Nov. 17, 1964 and 696976, Nov. 3, 1964. They also overlap patents issued to competitors (e.g. 719693 and 681760), and application 081556 of the applicant). These suggest questions of extension of monopoly, double patenting, and Section 63(2). Again, however, we see no need to explore those issues.

For the reasons indicated above, the Board is of the opinion that all of the claims should be refused.

Gordon A. Asher,
Chairman,
Patent Appeal Board.

I concur with the findings of the Patent Appeal Board. The claims are refused. The applicant has six months within which to appeal this decision as provided in Section 44 of the Patent Act.

Decision accordingly,

A.M. Laidlaw,
Commissioner of Patents.

Dated at Hull, Quebec
this 13th. day of
August, 1974.

Agent for Applicant

Marks & Clerks
Ottawa, Canada