Misuse of The Steenbook Inventions

THE POUNDATION'S ADMINISTRATION OF THE STRENBOCK PATENTS.

Organisation of the Poundation.

The Foundation was organized in 1925. Dr. Steenbook had prior therete made the inventions which later eventuated into the Steenbook patents, and had applied for patents thereon. He realized that these inventions had great commercial possibilities. He did not wish personally to benefit by his inventions and wished to assign them to the University. The Board of Regents of the University realized at the outset that they were not equipped to administer and commercially develop patents. Consequently, as a result of discussions by Dr. Steenbook, the University authorities and certain alumni of the University, the Foundation came into being. Its purposes, as defined in its charter are to

"promete, encourage and aid scientific investigation and research at the University of Wisconsin by the faculty, staff, alumni and students thereof ...".

Upon the inception of the Foundation, Dr. Steenbock assigned to it his then pending applications for patents. The Foundation started with a fund of \$900, representing \$100 contributed by each of the nine original members of the Foundation. Its sole assets were these \$900 and Dr. Steenbock's patent applications.

The Foundation commenced operations with no business organization, its affairs being handled by some of its individual Trustees. After a short period of such operation Dr. H.L. Russell, formerly Dean of the Agricultural College of the University of Wiscensin, became Director of the Foundation.

Since that time the Foundation has built up an organization consisting primarily of research, business and legal departments. Offices are maintained in Madison, Chicago and New York. In addition to the business office in Madison, the laboratory and its staff is located there. The present Trustees and officers of the Foundation are:

George I. Haight, President,
Thomas E. Brittingham, Jr., Vice President
L. M. Hanks, Secretary and Treasurer,
Timothy Brown, Vice President and Asst. Secretary,
W.S.Kies,
D.A.Grawford,
Judge Evan A. Evans.

Dr. Steenbock's inventions were the result of a long and painstaking period of research at the University of Wisconsin. He had been studying in the general field of animal nutrition, in which these inventions lie, for many years. Particularly, he had been concerned with the cause of loss of calcium from the body, the nature and storage of Vitamin A and the requirements for growth. The story of the inventions really commences in 1913 when Dr. Steenbock observed the effect of sunshine upon a goat when in pasture, in connection with the goat's retention of calcium in the body. The inventions of the Steenbock patents were, therefore, in no sense accidental or unrelated to Dr. Steenbock's research work, on the contrary, they were the culmination of a long period of careful research by him.

Broad scope of the Steenbock patents.

Dr.Steenbock's inventions, being basic and pioneer in character, were also of very broad scope. It was early apparent

that these inventions would find commercial application in connection with a wide variety of products, including many different kinds of foods and pharmaceutical preparations. It thus was clear that the commercial development of the inventions and the patents that issued thereon would involve not simply licensing arrangements with one specific industry, or even perhaps with a few concerns in one specific industry, but would involve a complex licensing program, covering a variety of branches of the food and drug industries.

Possible misuse of the Steenbock inventions.

It was also early apparent, long prior to the issuance of the first Steenbook patent, that the Steenbook inventions were capable of misuse by quacks and others, and unless properly administered would constitute a tool in the hands of fraudulent advertisers and unscrupulous business men. The inventions, having been among the most important inventions made in twenty-five or more years, received a very considerable amount of publicity, both in the lay press and in technical journals. The nature of the inventions was such that they peculiarly lent themselves to unscrupulous use, - that is, a particular food substance, when treated by ultra violet rays, would not be changed in taste, color, smell or other physical characteristics. The only way the increase in Vitamin D content of such a treated food could be determined was by a complicated biological assay, involving the use of rats and taking a considerable period of time. On the other hand, at the time of these discoveries vitamins were becoming popular in the public eye and

many manufacturers of a variety of foods and medicinal products were anxious to seize upon the inventions and exploit them to the detriment of the public.

As illustrative of this character of fraudulent promotion, Dr.Russell tells a story. One day, in the early history
of the Foundation, he was in Chicago, walking down La Salle
Street. He saw a group of people clustered around a display
window in which there was offered at \$1.00 per bottle some sort
of purported medicinal agent, which in its glass jar had been
treated in the display window with the rays of an ordinary electric light bulb. The medicine was blatantly asserted as being
a cure for a variety of human ailments.

Steps taken by the Foundation to prevent misuse of the Steenbook inventions and to protect the public.

Realizing early in the history of the Foundation that
the Steenbook patents were potentially an instrumentality of
fraud in the hands of dishonest manufacturers, the Trustees laid
down and ever since the organization of the Foundation have followed several policies, all of which have been designed to protect
the public. These policies are:

- 1. Limiting licenses to proper carriers for Vitamin D.
- 2. Controlling the advertising of licensees so as to prevent false, fraudulent and exaggerated advertising claims by appropriate clauses in license agreements.
- Controlling the Vitamin D potency of licensed products by appropriate provisions in license agreements.
- 4. Testing of licensed products by extensive biological assays in the Foundation's own laboratory.
- 5. Carrying on clinical experiments in connection with various Vitamin D preparations.

6. Education of the public as to the need for Vitamin D and advantages of its use.

(1) Limiting licenses to proper carriers for Vitamin D.

It has always been the feeling of the Trustees that Licenses under the Steenbook patents should be limited to proper carriers for Vitamin D. Generally speaking, desirable carriers are those foods which are consumed extensively by infants and children (where Vitamin D is needed most), and which are consumed regularly as part of the daily dist. The Foundation has always considered milk, bread, cereal breakfast foods and certain accessory food products as the most desirable carriers for Vitamin D in the food field. Since its organisation it has been hundreds of times besieged by inquirerers or applicants for licenses for the use of the process in connection with a variety of different things. Hundreds of these applications have been rejected because the product in question was an improper carrier, primarily for either one or more of the following reasons, namely, (1) that the product was not customarily consumed regularly and by the class of individuals, i.e., infants and children for which it would be most beneficial, or (2), in connection with inquiries relating to the direct use of ultra violet rays on a product (rather than the incorporation, for example, of irradiated ergosterol therein), because the product contained little or no pro-vitamin, and, therefore, application of ultra violet rays to it would not produce any appreciable quantity of Vitamin D there; and (3) that Vitamin D would not be stable in the proposed carrier. Examples of inquiries and applications for licenses which have been rejected by the Foundation, correspondence relating to which is in the Foundation's files, are the following:

Chewing gum tooth paste pretsels beer whiskey coffee pillows clothing sugar vanilla ext
bath salts coconut mil
massage oils alphalfa (i
bed sheets flax seed
cigarettes vegetables
smoking tobacco malt syrup
table salt sorghum
sausage fresh meats

vanilla extract
coconut milk powder
alphalfa (for animal use)
flax seed
vegetables
malt syrup
sorghum
fresh meats
a variety of unactivatable
animal feeds.

In turning down many applications for licenses regarding products such as those listed above, the Foundation, of course,
refused many thousands of dellars of license fees and royalties.
In some instances the rejections required extensive arguments
with the applicants. Some of these applicants were sincere in
desiring to improve their products by irradiation thereof or by
adding Vitamin D thereto. Many, however, desired to irradiate
or fortify their products purely for the advertising value thereof,something to talk about in advertising,- rather than from the
standpoint of actually improving the nutritious qualities of
their products.

In addition to the foregoing, the Foundation has found it necessary to reject a number of applications for licenses for legitimate and proper Vitamin D carriers upon the ground that the applicant was not willing to add sufficient Vitamin D to the product so that the Vitamin D would be of any benefit to the consumer thereof. The Foundation has been steadfast, however, in requiring that if its licensees do use Vitamin D in their products, there must be sufficient Vitamin D present so as to be of substantial benefit to the consumer.

(2) Controlling the advertising of licensees so as to prevent false, fraudulent and exaggerated advertising claims by appropriate clauses in license agreements.

The advertising control feature of the Foundation's licensing program needs little comment. Obviously, particularly in the early days of the Foundation, knowledge regarding various vitamins had not developed to the extent where it has today, and the functions of the various vitamins were not widely known. Consequently this advertising centrol probably meant more in the beginning of the Foundation that it does today. However, it was and is an important feature of the Foundation's control function, designed solely from the standpoint of protecting the public from false, exaggerated and unwarranted advertising claims, based upon the Vitamin D content of licensed products.

(3) Controlling the Vitamin D potency of licensed products by appropriate provisions in license agreements.

ments to specify the levels of potency or ranges of petency for licensed products. The purpose of this has been, on the one hand, to prevent a manufacturer from adding such a negligible quantity of Vitamin D so as to be of no practical benefit to the consumer; and on the other hand to discourage manufacturers from fortifying food products to therapeutic or medicinal levels, and thus making those food products in effect medicines. In the pharmaceutical field, the Foundation has also controlled the potency and, in some instances, the dosages of licensed products. Licensed Vitamin D pharmaceuticals were kept in range of unitage so they could serve both as therapeutic and prophylactic agents, always, however, kept in line so as to prevent overdoses of toxic amounts of Vitamin D.

(4) Testing of licensed products by extensive biological assays in the Foundation's own laboratory.

Since, as pointed out above, neither the presence of Vitamin D nor the amount of Vitamin D extant in a product can be detected except by animal tests, and since Vitamin D, either when produced by direct irradiation of the product or when added to the product in concentrated form, does not affect the color, taste, smell or other physical characteristics of the product, the Trustees felt it their duty at the outset to test products of licensees for Vitamin D content as part of the Foundation's control function. Up to June 30th, 1942, the Foundation had expended \$284,373.78 in maintaining and operating its control laboratory for the purpose of testing licensed Vitamin D products. An average of 20,000 white rats per year are used in this work. To date over 132,000 white rats have been used in the Foundation's laboratory on Vitamin D assay work. There are now weven employees engaged in assisting in the operation of the Foundation's laboratory. In addition to the Foundation's own laboratory, twelve other laboratories, located from coast to coast, have at the Foundation's expense done continuous testing work for the Foundation on perishable food products, primarily Vitamin D milk which could not be transported over great distances for testing in Madison.

In addition to the assaying of lisensed products the Foundation has done extensive work in its own laboratory on other phases of the subject. For example, the first standard Vitamin D preparation in the United States was made and standard-

ised in the Foundation's laboratory in 1930. The first standard unit for Vitamin D,- the Steenbook unit,- was formulated and announced in 1930 by the Foundation. The Foundation has coeperated with manufacturers of irradiating equipment, particularly irradiators adaptable for the treatment of fluid and evaporated milk, in designing and testing such equipment for efficient operation. Also, the Foundation has done extensive work in its laboratory in determining the stability of Vitamin D in many food and pharmaceutical preparations.

(5) Carrying on clinical experiments in connection with various Vitamin D preparations.

It has been the Foundation's policy from its inception not to grant licenses under the Steenbook patents until the licensed product has been demonstrated to be clinically effective. Extensive clinical work was carried on with Viosterol, today one of the most widely used forms of Vitamin D. before that product was permitted to be introduced upon the market by the Foundation's pharmaceutical licensees. The same is true with regard to irradiated Vitamin D milks, both fluid and evaporated. Much of this clinical work has been carried on by licensees of the Foundation. or groups of the Foundation's licensees, such as the individual pharmaceutical mamufacturer, and for the evaporated milk licensees, the Irradiated Evaporated Milk Institute. However, the Foundation on its own has conducted extensive clinical tests. Up to June 30th, 1942, \$170,834.53 had been expended or committed to be expended by the Foundation for clinical tests on Vitamin D products.

(6) Education of the public as to the need for Vitamin D and advantages of its use.

a staff headed by Dr. Scott, one of the primary functions of which has been to disseminate information concerning Vitamin D and Vitamin D products to the public and medical profession. These staff members have done a great deal of work in contacting the medical profession both individually and in group meetings and lecturing to groups of laymen, such as school groups, Parent Teachers Association groups, elub groups and others. Further, the Foundation has for the past several years spent between \$50,000 and \$60,000 a year in advertising, partly in medical journals and partly in lay publications, the purpose of the advertising being to acquaint and inform the public of the value of and need for Vitamin D.

The result of the Foundation's educational and prometional work on Vitamin D has of necessity been to increase the extent of knowledge of that subject. In the language of Dr.Philip C.Jeans of the University of Iowa Medical School, one of the most prominent clinical investigations of Vitamin D in the United States, when he testified in the Foundation's litigation in Californias

"And the knowledge on the part of physicians and of parents has increased to the extent that probably there exists now few mothers in this country and certainly no physicians who do not know that Vitamin D in some form is a necessary part of the infant's regimen".

Decrease in the incidence of rickets and tetany (two Vitamin D deficiency diseases) in the past twenty years.

It is generally now accepted by the medical profession

that during the past 20 years the incidence of rickets and tetany have greatly decreased. Dr. Jeans, referred to above, testified in Galifornia that the decrease has been a gradual one, starting in the early 1990's, and that the decrease is now so great that we see practically no active rickets in babies at the present time. He stated:

"It is most difficult to find satisfactory material with which to do our teaching to the medical students for both rickets and tetany".

The making of the Steenbook inventions and the Foundation's work in administering the Steenbook patents on those inventions, including its educational program have not, of course, been the only factors in the decrease of rickets referred to by Dr. Jeans. However, they have without question been important factors. Prior to the Steenbock inventions practically the only known rich source of Vitamin D was cod liver oil. This was a foul tasting product, particularly in those days and could not be tolerated by large numbers of infants and children. Dr. Steenbook's inventions made available to the public not only Vitamin D foods, such as the Vitamin D milks, but also the product Viosterol, a tasteless, odorless, highly potent antirachitic which could be and has been widely administered as a pharmaceutical preparation to infants and children. The availability of Viosterol as such an antirachitic and the availability of Vitamin D foods, particularly fluid and evaporated milks, on a wide scale have undoubtedly been important contributions to the decrease in rickets.

The Foundation has no monopoly on Vitamin D.

In the past many persons have apparently been under the

false impression that the Foundation, through its ownership of the Steenbock patents, "has a monopoly on Vitamin D". This is not the fact. The fact of the matter is that prior to Dr. Steenbock's inventions cod liver oil had long been known as the most important source of Vitamin D, and notwithstanding that the Steenbock inventions made an important contribution in supplementing end liver oil with Viosterol, Vitamin D fortified foods, etc., the fact remains that even today cod liver oil is probably the most widely used source of Vitamin D. This is particularly true when fields of animal and poultry nutrition, as well as human nutrition and medicine, are considered. Even today in the medical and popular literature cod liver oil is undoubtedly more frequently referred to as a rich source of Vitamin D than any other product.

Further, there are today on the market many other Vitamin D preparations not made under the Steenbook patents. In the fish liver oil field, in addition to cod liver oil and concentrates made from it, there are other fish liver oils and concentrates made from them which are migh in Vitamin D. Livers of the turns, shark, dog fish and other fish contain varied quantities of Vitamin D, and these products have during the past 10 or 15 years come into fairly wide commercial use. Also, there are today available upon the market other forms of what might be called synthetic Vitamin D, that is, there are processes for activating ergosterol and other pro-vitamin substances which do not make use of ultra violet rays, and do not come under the Steenbook patents. Illustrative of these are the activation processes commercially used today by General Mills, Inc., Minneapolis, Minn., and Mutrition Research Laboratories, Chicago, Ill.

In view of the foregoing it is correct to state that the Poundation through its Steenbook patents merely controls one method of producing Vitamin D, and in no sense does it have any monopoly - patent menopoly or otherwise - on Vitamin D.

The use of revenue produced by the Steenbook patents.

The Foundation has, of course, received substantial royalties from the Steenbook patents. These royalties on June 30th, 1942, aggregated \$9,915,887.45. The net revenue of the Foundation, however, over and above operating expenses and a share of the royalties to Dr. Steenbook, has been used in two ways: first, for the support of research at the University of Wisconsin, and second, for the building of a permanent fund for research at the University of Wisconsin. The policy of the Trustees, except during an emergency two year period (1933-1934), has been to give the University for research every year the investment income on the Foundation's capital fund. During the two year period mentioned above, however, when the University was unable to obtain funds from the Legislature for carrying on its research program, the Foundation came to its aid and dipped into its capital fund for this purpose. Up to June 30, 1942, the total amount of money turned over to the University and allocated to it (including the grant for 1942-1943), aggregated \$1,767,620.65.

The story of what the Poundation has meant to the University is best expressed by a memorandum prepared by Dean Fred of the Graduate School of the University of Wiscensin in July, 1941, copy of which memorandum is attached hereto. In order to

bring Dean Pred's memorandum up to date it should be mentioned that at the present time over two-thirds of the research projects at the University of Wisconsin being conducted on funds supplied by the Poundation are directly or indirectly related to the war effort. As illustrative of some of these projects may be mentioned the production of nitric acid and other war chemicals used in explosives and otherwise; the production of synthetic rubber; and the production of butyl alcohol, acetone and other solvents used extensively in war materials.

Other developments administered by the Poundation.

As a result of the Foundation's administration of the Steenbook patents a going concern has been created. Following the original purpose of its organisation, the Foundation has accepted and commercially developed other inventions which have been of substantial benefit to the public. An illustration is the work of Professor Hart in developing the combination of iron and copper for use in the treatment of secondary anemia. This invention has been developed commercially to a substantial extent and these copper-iron compounds are used extensively today by the physician in the theatment of anemia.

Another development now in the preliminary stages is Dr. Mohs' treatment of surface cancer. A new development just starting is the work of Professor Link and his associates in isolating from sweet clover and later synthesising a chemical compound for use as an anti-blood coagulant in the treatment of post operative thrombosis and other diseases.

Another invention, not in the field of nutrition or medicine, now starting to be developed by the Foundation is Professor'Allen's work in the preparation of a high effective insecticide from a botanical, sabadilla seed. The insecticide is of particular importance today since the botanical from which it is derived can be grown domestically and since the principal toxic ingredient of insecticides heretofere on the market, namely, pyrothrum, largely heretofere imported from Japan, is now relatively scarce. The armed forces of the United States will probably in the coming year require for their own use practically all of the pyrethrum anticipated to be imported from South Africa.

In addition to the foregoing, attention is called to
the invention of Professors Hart, Clifcorn and Griem on the stabilisation of salt and other feed materials. For years common salt
has been recognized as an excellent carrier of iodine needed for
the prevention of goiters in humans and live stock. Salt and other
feed materials to which iodine had been added, however, were found
to rapidly lose this element and frequently such products contained much less iodine than stated on their labels. The stabilisation method of Professor Hart and his associates has been patented
by the Foundation and is today extensively used by salt producers
and producers of various other feed mixtures. The financial returns
on this invention are very small compared with the returns on the
Steenbock invention. Nevertheless the invention has been an important contribution to the public welfare and is today recognized by
the American Medical Association as the best method of fixing iodine

in salt and other feed materials.

In the development of other inventions, of which the foregoing are illustrative, the Foundation has followed a similar pattern of control as in the case of the development of the Steenbock inventions. Extensive testing work, both chemical and biological, is being done continusously in the Foundation's aboratory on copper-iron compounds, stabilized iodized salt and other feed mixtures, etc. Similar controls of potencies, advertising claims and other matters are exercised by the Foundation in connection with these inventions, as in the case of Vitamin D. Similar educational work is also carried on.