Smith, Kline & French Laboratories v. Clark & Clark, 62 F. Supp. 971 (D.N.J. 1945)

US District Court for the District of New Jersey - 62 F. Supp. 971 (D.N.J. 1945)
September 1, 1945

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62 F. Supp. 971 (1945)

SMITH, KLINE & FRENCH LABORATORIES
v.
CLARK & CLARK et al.

No. C-2311.

District Court, D. New Jersey.

September 1, 1945.

***972 *973** Grover C. Richman, Sr., of Camden, N. J. (George J. Harding and George A. Smith, both of Philadelphia, Pa., of counsel), for plaintiff.

Morton C. Haight, of Pitman, N. J. (Nelson Littell and V. Alex Scher, both of New York City, of counsel), for defendants.

FORMAN, District Judge.

This is an action brought by Smith, Kline & French Laboratories, a Pennsylvania corporation, assignee of Gordon A. Alles, of Monterey Park, California, to whom United States Letters Patent No. 1,879,003 was issued on September 27, 1932. The plaintiff charges the defendants Clark & Clark, a New Jersey corporation, Charles ***974** L. Morris, Robert Brinton Morris trading as Professional Laboratories, David M. Olmstead, Benjamin Zirin and Standard Medical Laboratories, a New Jersey corporation, with infringement of the said patent and unfair competition, and seeks profits and damages arising therefrom.

An answer was filed by Clark & Clark, Charles L. Morris, and Robert Brinton Morris trading as Professional Laboratories, who by way of counterclaim seek injunctive relief and damages against the plaintiff. The suit is not pressed against David M. Olmstead, Benjamin Zirin and Standard Medical Laboratories.

The answering defendants take the position that they did not infringe the plaintiff's patent for the reason that it lacked validity in that: (1) Alles was not the original inventor; (2) the composition claimed was not new or novel in that one skilled in the art could ordinarily produce the same; (3) that the descriptions contained in the letters patent are ambiguous and indefinite and do not disclose the invention in clear and concise terms so as to enable one skilled in the art to produce the same; (4) that the claims of the patent are excessive, vague, ambiguous, and indefinite and (5) that the composition is an unpatentable combination of old and well-known elements produced in an obviously customary manner.

Other contentions raised at the trial were that the disclaimer filed by Alles on August 29, 1934, is invalid; the patent and the claims of the disclaimer are invalid for the reason that no invention is involved to find that an old

product works for a known use, particularly in a field where it was known that products of the type involved were useful. The defendants further contended at the trial that if it is assumed that the discovery is patentable as an old product for a known use, then the claims of the disclaimer were invalid because they failed to "particularly point out and distinctly claim" the invention as required by law.

In addition to a denial of infringement upon their part, the defendants likewise denied that they have been guilty of unfair competition as alleged by the plaintiff. Affirmatively, the defendants insist that they are entitled to recover against the plaintiff their provable damages for unfair competitive practices upon the part of the plaintiff, which forms the substance of their counterclaim.

The invention relates to a composition of matter purporting to be useful for therapeutic purposes. The specifications describe the invention and state that the composition is physiologically active and produces effects in animals and man similar to the effect of the salts of ephedrine.

In his patent Alles originally claimed:

"1. As a new composition of matter, a salt of 1 phenyl-2-aminopropane.

"2. As a new composition of matter, the hydrochloride of 1-phenyl-2-aminopropane."

His disclaimer follows:

"He disclaims so much of claim 1 of said patent as is in excess of the following:

"`As a physiologically active therapeutic agent capable of producing effects in animals and man similar to the effect of salts of ephedrine, a salt of 1-phenyl-2-aminopropane.'

"He disclaims so much of claim 2 of said patent as is in excess of the following:

"`As a physiologically active therapeutic agent capable of producing effects in animals and man similar to the effect of salts of ephedrine, the hydrochloride of 1-phenyl-2-aminopropane.'"

The composition 1-phenyl-2-aminopropane is also chemically known as phenylisopropylamine and benzylmethyl carbinamine.

The salts of the composition 1-phenyl-2-aminopropane, which is the subject of the Alles patent and of this action, was in 1938 given the generic name "amphetamine sulfate" by the American Medical Association, by which name it will be generally referred to hereinafter. It is the identical compound which is prepared and sold by the plaintiff under the brand or trade name of "Benzedrine" or "Benzedrine Sulfate."

In Part I of this opinion we will discuss the patent phase of this case and in Part II we will take up the phases of unfair competition.

Part I

The Patent

Amphetamine sulfate is the salt of 1-phenyl-2-aminopropane. It is obtained by Alles by means of a method of synthesis described by him in the specifications of the patent and converted into a salt which is pure and suitable for the purpose of therapeutic administration. The conversion of the product into the salt is effected by neutralizing the impure product with an acid. ***975** The conventional method of converting bases into salts is by the

addition of an acid. Not all bases are capable of such transformation. It is impossible to convert some bases into any solid form such as a salt. Others cannot be so converted by the use of an acid. It is a specific matter for a specific substance and a specific acid as to whether or not the salt thereof is crystallizable or is obtainable in solid form free from other contaminating substances. Experimentation is requisite to determine which method of preparation is suitable to get a desired result.

Amphetamine sulfate may be said to be more closely allied with the field of sympathomimetic amines than with any other field in medicine, pharmacology or chemistry. It is the knowledge of the art in this field that is advanced as the prior art upon which was based the discovery of amphetamine sulfate for therapeutic purposes.

The autonomic nervous system, by which every single structure of the body is brought under a dual control, consists of two branches, the central nervous system and the sympathetic nervous system. There is also a division of the sympathetic nervous system known as the parasympathetic nervous system.

The central nervous system consists of the brain and spinal cord, and some structures of the brain are independent of the sympathetic nervous system. In the central nervous system is generated, among others, mood, feeling of energy, feeling of sleeplessness, capacity to have appetite for food or sex. Examples of diseases of the brain are epilepsy and Parkinson's disease.

The sympathetic nervous system stems from the central nervous system and starts from points of the spinal cord and a structure at the lower part of the brain and winds its way through every organ of the body. It extends peripherally to the eye, to the skin, to every blood vessel, to the heart, to the lungs, to the gastro-intestinal tract and through every portion of the organism.

The parasympathetic nervous system innervates the active organs of the body, such as the stomach, the intestines, the uterus, the prostate or principally those organs which have smooth muscle tissue.

A sympathomimetic amine is a substance which stimulates the peripheral parts of the sympathetic nervous system. Examples of this action are constriction of the blood vessels, increased rate and force of the heart beat, a rise in blood pressure, dilation of the pupils of the eye, relaxation of the bronchial muscles, a rise in blood sugar, increased metabolic rate, decreased activity of the gastro-intestinal tract of the stomach and intestines.

Prior Art

The following literature constitutes the prior art, some of which was offered by the defendants as anticipatory of the Alles' claims:

1. "On a Few Derivatives of the Phenylmeth-Acrylic Acid and of the Phenyl-Iso-Butyric Acid," by L. Edeleano, published in the Berichte der Deutschen-Chemischen Gesellschaft (Ber. Dtsch. Chem. Gesell. 20:616, 1887).

2. "Handbuch der Organischen Chemie," by Dr. F. Beilstein, Dritte, Umgearbeitete Auflage, Verlag von Leopold Voss (Hamburg und Leipzig), 1896 and Vierte Auflage, Die Literatur Bis 1, Januar 1910 Umfassend, Verlag von Julius Springer (Berlin), 1929.

3. "Chemical Structure and Sympathomimetic Action of Amines," by G. Barger and H. H. Dale, published in The Journal of Physiology (Cambridge University Press, London), Vol. XLI, 1910-1911, p. 19 et seq.

4. "Adrenaline and Other Derivatives of Ethylamine," by Percy May, published in The Chemistry of Synthetic Drugs (Third Edition, Revised), 1921 (Longmans, Green and Co., London), p. 129 et seq.

5. References to the publications of Doctors K. K. Chen and Carl F. Schmidt may be found in the bibliography of their article entitled "Ephedrine and Related Substances," published in Medicine, Vol. IX, No. 1, February, 1930.

6. "The Beckmann Rearrangement Involving Optically Active Radicals," by Lauder W. Jones and Everett S. Wallis, published January 8, 1926, in The Journal of the American Chemical Society, Vol. XLVIII, January-June 1926, p. 169 et seq.

7. "dl-B-Phenylisopropylamine and Related Compounds," by Donald Holroyde Hey, published in 1930 in the Journal of The Chemical Society, London (J. Chem. Soc., p. 18 et seq.).

1. Edeleano-1887

In 1887, Edeleano, a German scientist, wrote a paper for the Berichte der Deutschen ***976** Chemischen Gesellschaft (Ber. Dtsch. Chem. Gesell. 20:616, 1887), in which he outlined a method of preparation of phenylisopropylamine C6H5CH2CH(CH3)NH2 and its analysis. He stated:

"The salts of the base are mostly very easily soluble in water, while the platinum double salt represents a compound difficultly soluble in water and crystallizing in matted small needles."

The synthesis of this product by Edeleano was purely a chemical attempt and involved no physiological testing. Edeleano's statement relating to the solubility of the salts of the phenylisopropylamine base did not carry with it

the procedure for the preparation of any salts of the base he described, nor did it describe any salt of phenylisopropylamine.

Alles makes no claim that he was the *first* discoverer or inventor of the base of this composition. Edeleano stated that he prepared the composition, provided a method for such preparation and described the completed product in certain respects. There is no question that Edeleano did prepare the base of this substance. He made no reference whatsoever to its use for any purpose. There appears no reason, nor the suggestion of one, that he worked with this base other than purely from a chemical standpoint. He entitled his article "On a Few Derivatives of the Phenylmeth-Acrylic Acid and of the Phenyl-Iso-Butyric Acid" and under the heading "Method of Preparation of Phenylmethacrylic Acid" set forth an account of what he did in his laboratory. He said nothing that gave rise to an inference that the substance had any effect or that it was useful for any purpose. Edeleano stated that the salts of the base were easily soluble in water, while the platinum double salts were soluble with difficulty.

From this the defendants ask us to infer that Edeleano actually prepared the identical salt of this base which Alles claims as a patent. It is obvious that Edeleano prepared certain salts of the base, but it is quite impossible to determine which salts he prepared. He did not describe the method of preparation of the "easily soluble" salt of the base with any characteristics by which it could be identified as a particular salt.

It appears that certain salts of this base are easily soluble in water, some are not so soluble and others are not soluble at all. Hence, there is no disclosure by Edeleano of any particular salt of the base. We cannot say that Edeleano experimented with the salts, much less that he particularly prepared a salt which would be useful for therapeutic purposes.

At this point, however, it is urged that the addition of sulphuric acid or hydrochloric acid to a base, in order to convert it into a salt, is a method used commonly by chemists, and that with the base described by Edeleano, together with the application of this well-known method of conversion, any skilled chemist could arrive at the composition which is the subject of this patent claim. A skilled chemist, following Edeleano's methods as described in his paper and applying the knowledge of his profession and of the art prior to Alles, might very well be able to produce a salt of 1-phenyl-2-aminopropane, but not a substance having the effects of the Alles' compound for therapeutic purposes. To prepare such a substance requires original experimentation on the part of the chemist as to effect of the substance upon animals and man. Edeleano's disclosure taught only the manner by which the base of the compound could be prepared and referred incidentally to two salts thereof without further identification. It is insufficient as an anticipation of a disclosure of effect and therapeutic usefulness of a certain salt of the base.

2. Beilstein 1896

As evidence of an ancient disclosure of the patent, the defendants directed attention to "The Handbook of Organic Chemistry," compiled by Beilstein, an encyclopedia of organic compounds, 1896 edition, in which was listed the base of phenylisopropylamine as follows:

"12 (a) Aminopropylbenzol (Phenisopropylamine) C6H5.CH2.CH(NH2).CH3. B. Beim Behandeln des Amids der Methylbenzylessigsaure mit (1 Mol.) Brom und (5 Mol.) Kalilauge (von 4%), unter Abkuhlen (Edeleano, B.20,618). Flussig. Siedep.: 203°."

Substantially the same content of the listing appears in the 1929 Edition of Beilstein. No mention is made in this later listing, the last to be published prior to the Alles patent, of the salt of phenylisopropylamine. Of course, these are only references to the paper by Edeleano and add nothing to the prior art.

***977 Adrenaline or Epinephrine 1895 to 1910**

In 1895, two English scientists, Mather and Schaffer, published a paper concerning the effects produced by the introduction into animals of an extract of the suprarenal glands. This extract consisted of a salt solution of the tissues of the glands that lie at the upper pole of the kidney. They described as effects a marked rise of blood pressure, which stimulated a great deal of interest at the time. Several physiologists and chemists succeeded within a few years in the isolation in relatively pure form of a solution containing the active principle of this extract. By the year 1901 it became known as adrenaline or epinephrine. A chemical composition for these compounds was soon developed and it became possible to produce them in the laboratory synthetically instead of taking them from the animal body.

Adrenaline was one of the first of the sympathomimetic amines. It had the disadvantages, for purposes of therapeutic use, of being ineffective orally and of having no prolonged action. The work in this field was therefore directed toward finding a compound of greater intensity of action, i.e., one that acts upon the sympathetic nervous system in smaller doses.

3. Barger and Dale 1910

In 1910, Barger and Dale published their article in The Journal of Physiology (Cambridge University Press, London, Vol. XLI, 1910-1911, p. 19 et seq.), wherein they described a series of tests of a large number of synthetic derivatives of this type in which they set up certain specifications that have stood the test of time. These compounds are known by the term "sympathomimetic amines," which was introduced by Barger and Dale and defined by them as "a term which indicates the relation of the action to innervation by the sympathetic system, without involving any theoretical preconception as to the meaning of that relation or the precise mechanism of the action." Their experiments were done upon animals whose spinal cords were cut at the base of the axis vertebra and the neural arch of the vertebra was removed. The brains of the animals were completely destroyed.

In their article Barger and Dale make the following statement:

"Taking B-phenylethylamine as our starting point, we investigated first the effect of varying the length of the side-chain. It was shown that lengthening the carbon chain of the purely aliphatic bases up to a certain point was attended with increase of activity. In the case of the fatty-aromatic base, however, we found that the side-chain of two carbon atoms gave the optimum of activity. Aniline, which has no side-chain, and is therefore a purely aromatic base, had none of the specific action; benzylamine had a mere trace; and aphenylethylamine, in which, again, only one carbon atom intervenes between the amino-group and the aromatic ring, was also very feebly active. Increasing the side-chain beyond two carbon atoms also resulted in a decline of activity, phenylpropylamine being much less active than phenylethylamine (Fig. 4). The optimum constitution of a fatty-aromatic amine for the production of the sympathomimetic action is, therefore, that which is found in adrenine itself, viz. a benzene ring with a side-chain of two carbon atoms, of which the second bears the amino group." At p. 29, supra.

They arrived at the following conclusions, among others, as a result of their experiments:

"(1) An action simulating that of the true sympathetic nervous system is not peculiar to adrenine, but is possessed by a large series of amines, the simplest being primarily fatty amines. We describe all such amines and their action as `sympathomimetic.'

"(2) Approximation to adrenine in structure is, on the whole, attended with increasing intensity of sympathomimetic activity, and with increasing specificity of the action.

"(3) All the substances producing this action in characteristic manner are primary and secondary amines. The quarternary amines corresponding to the aromatic members of the series have an action closely similar to that of nicotine.

"(4) The optimum carbon-skeleton for sympathomimetic activity consists of a benzene ring with a side-chain of two carbon-atoms, the terminal one bearing the amino-group. Another optimum condition is the presence of two phenolic hydroxyls in the 3:4 position relative to the side-chain; when these are present, an alcoholic hydroxyl still further intensifies the activity. A phenolic hydroxyl in the 1 position does not increase the activity." Pp. 58, 59, supra.

***978** Defendants claim that there is an insignificant distinction between the disclosure by Barger and Dale and the Alles compound. In conclusion No. 4, above, Barger and Dale showed that optimum activity in pressor amines is found in those structures which have a benzene ring and a carbon side-chain with the amino group attached to the second carbon atom in the chain. They investigated the varying length of the carbon chain to determine the optimum constitution of the fatty-aromatic amine for the production of sympathomimetic activity. They concluded that phenylethylamine, the

structure of which consists of a benzene ring with a side-chain of two carbon atoms with the amino group on the second carbon atom constituted this optimum structure. It was determined by them that specifically an increase in the side-chain beyond two carbon atoms resulted in a decline of activity. This was proved when phenylpropylamine was used which has a chemical structure including a side-chain of three carbon atoms with the amino group attached to the terminal carbon.

Alles found optimum activity in phenylisopropylamine (1-phenyl-2-aminopropane) which is a chemical structure in which is included a side-chain of three carbon atoms, but the amino group is attached to the middle carbon atom. This structure is different from that of phenylpropylamine and was not considered by Barger and Dale in their experimentation. They omitted to investigate the potentiality of the compound constructed by Alles. They fell short of disclosing the optimum activity later developed by Alles when he proved that phenylisopropylamine had a greater pressor activity than any other compound theretofore considered. They confined their research to sympathetic effects in the field of sympathomimetic amines.

It must also be observed that no intimation as to effects on the central nervous system is given by Barger and Dale. Their experiments precluded any such effects because they worked on animals devoid of central nervous systems.

4. Percy May 1921

In 1921, a volume entitled "The Chemistry of Synthetic Drugs" was published (Longmans, Green and Co., London). The author, Percy May, in a chapter concerning "Adrenaline and Other Derivatives of Ethylamine,"

summarized the literature on the subject. He added no new data but quoted the conclusions of Barger and Dale in their entirety.

5. Chen and Schmidt 1923

In the year 1923, Dr. Carl F. Schmidt, presently Professor of Pharmacology at the University of Pennsylvania, went to Peking, China, to take temporary charge of the Department of Pharmacology in the Peking Medical College. His work involved research in Chinese drugs. Several Chinese drugs were studied with no noteworthy results.

At the end of that year a young Chinese scientist, K. K. Chen, a graduate in chemistry of the University of Wisconsin, went to Peking to work with Dr. Schmidt. Although the Chinese thought that their drugs were potent, Dr. Schmidt had been unable to confirm this conception. At one of his family conclaves in China Dr. Chen's uncle, a druggist, upon hearing this view, became rather indignant and stated that he knew from personal experience that there was at least one Chinese drug that was potent ma huang.

Dr. Chen brought some of this drug with him to Peking and an extract of it was injected into an animal, producing a sharp rise in blood pressure. This action was surprising, for the experiments conducted by Dr. Schmidt involving the injection of many plant extracts into animals always produced a drop in blood pressure.

Dr. Chen succeeded in isolating crystals from the plant, ma huang, which crystals he identified as an alkaloid. Several experiments were made with the crystals and it was found that the active principle was a sympathomimetic substance. Experiments with the drug upon patients proved that it was effective and had a relatively low toxicity.

A search for a name for the drug resulted in the discovery that it had already been isolated in 1887 by a Chinese chemist named Nagai, who had called it ephedrine. The drug was brought to the United States in 1924 and results of various clinical studies were published by Chen and Schmidt from time to time thereafter. (References to these publications may be found in the bibliography of a lengthy article published by them in Medicine, Volume IX, No. 1, February 1930.) Since 1924 the drug has been in use quite extensively.

Although ephedrine was isolated and its chemical structure known for many years, it was regarded as a very toxic substance ***979** until it was introduced in this country by Chen and Schmidt. It had several advantages over the other drugs in the field, like adrenaline or epinephrine, in that it produced the same effects when taken orally and its duration of action was a matter of hours rather than minutes. Physiologically, ephedrine stimulates the peripheral parts of the sympathetic nervous system, resulting in constriction of blood vessels, acceleration of the heart, dilation of the pupils, decreased movement of the gastro-intestinal tract and relaxation of that tract and the bronchi. It has certain stimulant effects upon the central nervous system previously not described in compounds of this series. These effects upon the brain cells are comparable with that of caffeine. They manifest themselves in restlessness, nervousness, tremors, anxiety, insomnia in some individuals, and in an appreciable number of cases, particularly in women inclined to be nervous, may lead to nausea and vomiting. A depressant action upon the heart muscle, similar to myocardial depressants, imposes a limitation upon the therapeutic usefulness of the drug. It is extensively used to shrink mucous membranes when congested. Ephedrine, being orally effective and possessing a duration of action, displaced adrenaline. Prior to its discovery, there existed no better compound having the action which adrenaline had upon the peripheral sympathetic nervous system. Compounds of the same

general type which had been made and tested were found to be weaker than adrenaline.

This work in ephedrine produced for the first time in the field of sympathomimetic amines not only effects upon the sympathetic nervous system but concomitant effects upon the central nervous system. However, it did not result in encouraging the exploitation of the latter effects, but rather regarded them as deleterious and to be diminished as far as possible or eliminated.

6. Jones and Wallis 1926

The next publication to be considered in the prior art of the Alles compound is a paper appearing in 1926 in the Journal of the American Chemical Society (J. Am. Chem. Soc., 48:169, January-June 1926), entitled "The Beckmann Rearrangement Involving Optically Active Radicals" by Jones and Wallis. This paper is based upon a thesis submitted by Wallis in partial fulfillment of the requirements of Princeton University for his degree of doctor of philosophy.

Jones and Wallis purported to have isolated the dextro-rotatory form of benzylmethyl-methylamine hydrochloride. The latter is the chemical equivalent of the hydrochloride of the dextro form of B-phenylisopropylamine or dextro amphetamine hydrochloride. They describe the properties of the product they allege they obtained as follows:

"d-Benzylmethyl-methylamine Hydrochloride, (C7H7) (CH3)CH.NH3Cl. When 1.296 g. of d-benzylmethylmethyl-isocyanate was placed in a small flask, together with 4 cc. of concd. hydrochloric acid a reaction started immediately, but progressed slowly. The flask was kept cool by allowing water to play over it. After an hour the two layers had disappeared, and

carbon dioxide ceased to be evolved. Near the end of the reaction the flask was warmed to 38°. The solution was diluted with water and extracted thrice with ether to remove any unchanged isocyanate. The ether extract gave no residue of isocyanate upon evaporation. The solution gave a rotation of +1.88° in a 200 mm. tube at 20°.

"The water solution was evaporated to dryness. A white, crystalline, hygroscopic salt was left. This was washed with ether and dried in the oven at 80°. The amount of chloride obtained was 1.25 g., melting at 147°. 1.20 g. dissolved in 25 cc. of water gave a rotation of +1.60° in a 200 mm. tube at 20°, (a)20° = +16.6°." at p. 180, supra.

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The defendants contend that Jones and Wallis in this work described the d-form of the hydrochloride of phenylisopropylamine and that it was known to Alles when he claimed to be the first to produce a salt of 1-phenyl-2-aminopropane. Furthermore, they claim that this disclosure sufficiently described a salt of 1-phenyl-2-aminopropane, so that any chemist could produce it from the directions of Jones and Wallis and the Edeleano publication.

A sharp issue is raised by the plaintiff on the question of whether Jones and Wallis actually obtained the substance they describe as d-benzylmethyl-methylamine hydrochloride. Alles testified that he produced d-benzylmethyl-methylamine hydrochloride, but that the constants in his compound were a melting point of 156° to 157° and an optical rotation of +26.6° at 20°, as against a melting point by Jones and Wallis of 147° and an optical rotation of +16.6° at 20°.

***980** He further testified that there were errors in the Jones and Wallis article which made it impossible for him to follow their directions and get the product they contend they produced. Alles' testimony is corroborated in

detail by Dr. George H. Connitt, a research organic chemist in the employ of the plaintiff.

Opposed to the above we have the testimony of Philip Sadtler, a consulting chemist on behalf of the defendants. He conceded that he had a financial interest in the termination of the case in favor of the defendants. It was his opinion that a skilled chemist would have had no difficulty in following the directions of Jones and Wallis and that they described accurately a process to produce dextro-benzylmethylmethylamine, although he had not personally attempted to produce it according to their formula.

The work of Jones and Wallis, like that of Edeleano, consisted of chemical tests of compounds for chemical and not for physiological purposes. They gave no intimation in their article of effects of their preparations or of therapeutic uses therefor.

The evidence on the accuracy or inaccuracy of the disclosures of Jones and Wallis comes from Alles, the plaintiff's employee Connitt, the financial intimate of the defendants, Sadtler, and the disinterested witness Dr. Schmidt, who also was queried as to the accuracy of the Jones and Wallis disclosure on his cross-examination by plaintiff's counsel.

When Dr. Schmidt was first approached upon this subject with the question: "Well, from your examination of the abstract would you have any doubt that Jones and Wallis described the preparation of the hydrochloride of 1-phenyl-2-aminopropane?" His answer was: "I would have none; I think they did, yes." (Record, p. 294)

Later in the same cross-examination Dr. Schmidt answered questions as follows:

"Q. The claim of the patent as originally issued called for a new composition of matter, a salt of 1-phenyl-2-aminopropane. Now, if Jones and Wallis in

1926 had produced the hydrochloride of 1-phenyl-2-aminopropane wasn't that a salt of 1-phenyl-2-aminopropane?

"The Witness: May I answer that in my own way?

"Q. You may. A. I would like to start out the answer by saying this was, as far as I know these were purely chemical attempts, it involved no physiological testing.

"The Court: You mean the attempts of Jones and Wallis?

"The Witness: And of Edeleano. A. (continuing) The compounds were made as purely chemical substances for chemical purposes, but not as far as I know for physiological purposes.

"Now, to decide on whether they were or were not identical with the Alles compound would involve specialized information about their chemical constants, such things as optical rotation, melting point and the different precipitation and solubility reactions. On that I am not competent to state even if I did have the information, which I have not, so the answer, I am afraid, would have to be I don't know." (Record, p. 299)

Again, on redirect, Dr. Schmidt testified as follows:

"Q. Dr. Schmidt, with reference to the dextro compound named in the Jones and Wallis abstract to which you were referred, do you know the boiling point of that compound? A. No, I do not, Mr. Harding.

"Q. Do you know its optical rotation? A. Only it must be to the right.

"Q. That is, you don't know what the figure would be? A. I do not, no, sir.

"Q. You only assume that Jones and Wallis probably referred to the compound that they named because they say so, then, is that true? A. Yes.

"Q. In other words, the constants they give, boiling point and rotation, may be incorrect? A. They may be, yes, sir." (Record, pp. 307, 308)

It would seem that Dr. Schmidt's categorical answer as to the Jones and Wallis disclosure, first given by him, was considerably weakened by his further testimony.

The attack upon the disclosure, it is true, comes from interested witnesses, Alles and Connitt, but they seem to be competent, qualified and able scientists, whereas the sole support for the defense comes from Sadtler, the quality of whose testimony is not impressive. Alles and Connitt supply the technical information of boiling points and optical rotations which Dr. Schmidt lacked. They are different from the constants of the Jones and Wallis disclosure in material aspects. Aside from the testimony of Sadtler, who admitted he did not attempt to make the Jones and Wallis product, we have no testimony to contradict Alles and ***981** Connitt. We are convinced that a skilled chemist, following the directions of Jones and Wallis, would not have obtained what they said they produced, and we are unable to find proof of anticipation upon their part of the Alles' hydrochloride of 1-phenyl-2-aminopropane and certainly no statement of uses or effects.

7. Hey 1930

There remains to be considered a publication by Donald Holroyde Hey, entitled "dl-B-Phenylisopropylamine and Related Compounds," which appeared in the Journal of the Chemical Society, London, in the year 1930 (J.Chem.Soc., p. 18, 1930).

Alles applied for his patent on September 2, 1930, and the plaintiff objects to the admission of the Hey publication for the reason that only the year "1930" appears in evidence as the date thereof. The plaintiff argues that it

may have been published on any day in 1930 subsequent to the date of the Alles' application and therefore is not properly admissible in evidence. At the termination of the article appears the notation "(Received, November 1st, 1929.)"

The publication is offered for the purpose of showing that Alles knew of the Jones and Wallis publication, for in an article written by him on the subject of "d1-Beta-Phenylisopropylamines," which appeared in the Journal of the American Chemical Society in 1932 (Am. Chem. Soc., 54:271, January-April, 1932), at page 273, he cited the Hey article as a report of a melting point of d1-b-phenylisopropylamine which was obtained from the reduction of phenylnitropropylene. Although the plaintiff may be technically justified in its objection, we prefer to consider the article as proffered by the defendants.

Alles claims that although he cited Hey as reporting a particular melting point for a certain compound, he was not cognizant of the publication's reference to Jones and Wallis at that time. If we assume that Alles knew of the reference in the Hey publication to Jones and Wallis, we fail to see how that strengthened the anticipatory effect of the Jones and Wallis publication, since its effectiveness or ineffectiveness as a publication of prior art anticipatory of Alles' claim does not depend upon the knowledge of Alles.

History of the Alles' Patent 1930

Gordon A. Alles, the patentee, obtained his degree of doctor of philosophy at the California Institute of Technology in 1926. He has worked in the fields of chemistry, physiology, pharmacology, experimental therapeutics, biology, and experimental medicine.

He became interested in making adrenaline derivatives in 1923 prior to the publications of the work of Doctors Chen and Schmidt. In 1924 he became associated as a research chemist with two doctors in Los Angeles who specialized in the field of allergic diseases, including hay fever and asthma.

After 1926, when the work of Chen and Schmidt had become publicized and ephedrine had been made available in small amounts, Alles turned his attention toward the preparation of compounds that could be used as synthetic substitutes of ephedrine in order to make a greater supply of such materials available with the objective of ascertaining whether a useful drug had been found in allergic diseases that filled the clinical needs of the doctors with whom he was associated. He made a survey of the literature then existent and concluded that it would be possible to make a chemical compound of phenylethanolamine which would produce similar results to ephedrine in therapy. However, when prepared in a pure state and suitable for therapeutic purposes, it was found that it produced the peripheral effects of ephedrine but failed in that it did not have its duration of action and its oral effectiveness. No effect upon the central nervous system was observed when the compound was administered, even in very large dosages.

Alles returned to the work after a lapse of a year spent in other research, reviewed the literature and set out to make another type of compound. This time he prepared the compound 1-phenyl-2-aminopropane in the form of its salts of a purity suitable for therapeutic purposes. He carried out experiments in 1928 in the Department of Physiology at the University of California and discovered 1-phenyl-2-aminopropane salts when injected into dogs and rabbits produced a blood pressure rise of long duration. He also noted that, unlike corresponding nearly related derivatives studied at the same time, this compound was orally effective in animals.

He was well acquainted with the effects of ephedrine sulfate and ephedrine hydrochloride because he had administered them to himself on several

occasions and was acquainted with the action on both the ***982** blood pressure and with regard to its other actions in the body.

Accordingly he self-administered 50 milligrams of 1-phenyl-2-aminopropane hydrochloride which he had prepared and also administered the same dosage to his associate. They observed that the effect upon the circulation consisted of a rise in blood pressure upon the first administration which was made by subcutaneous injection. This rise was both marked and prolonged, lasting for a period of about 8 hours. Alles found that when he went home he could not fall asleep and was awake the whole night. His blood pressure, taken upon his arrival at the laboratory the following morning, had returned to normal.

A few days later the experiment was repeated. This time Alles took the same dosage orally and his blood pressure and circulation were watched by his associate, Dr. Miller. Again there was a similar rise in blood pressure of long duration. After a day of observation he again failed to get any sleep during the night. This made him realize that the drug had a waking effect that was many times that which he had observed with ephedrine in similar dosage.

After these preliminary observations on himself Alles directed his interest toward the trial of the drug in asthma, which was the principal purpose for which he had been working upon it. Two asthmatic patients placed themselves at his disposal. They had been victims of the disease for long periods of time. The first one had suffered for the previous three years and Alles administered to him 50 milligrams of 1-phenyl-2-aminopropane hydrochloride by mouth. After an hour his blood pressure started to rise and continued at a high level during the period of observation of the next six hours. The patient was very wakeful and alert, talked a great deal, and his blood pressure was taken from time to time. At the end of the day he was sent to his home and requested to return the next morning. He reported that he had not slept at all during the night but that he felt very well in spite of

the lack of sleep. His asthma had been relieved during the whole afternoon and night, apparently as a result of the administration of the drug.

The second asthmatic patient, a woman with a consistent asthmatic attack covering the previous year, also found relief from the asthma and a marked wakefulness as a result of the administration of the drug. It was necessary to administer phenobarbital to this patient to induce sleep.

From his experimental work Alles says he clearly recognized that this was the first time in any compound other than ephedrine that there was evidence of two kinds of effect, typical of ephedrine from the standpoint of pharmacology and therapeutics, namely, that the compound exerted an effect upon the peripheral sympathetic nervous system, and also a very marked effect upon the central nervous system. This was in contrast with all previously known adrenaline-like compounds.

Later Alles experimented with four individuals, including himself, to determine the amount of 1-phenyl-2-aminopropane salt that was required to stimulate the central nervous system to effects that would persist through the day only and allow the individual to sleep at night. He administered 5 and 10 milligram dosages of 1-phenyl-2-aminopropane salts, daily, in the morning, and observed the changes of behavior during the course of the day. It was found that such dosages produced a tendency to stay awake later at night, but all of the individuals, including Alles, found that they were able to sleep successfully through the night. Such dosages on later experimentations with asthmatics were disappointing in the effect because they were insufficient to obtain effect upon the peripheral sympathetic mechanisms to satisfactorily relieve the asthma. Further experiments were made to study other peripheral sympathetic effects of 1-phenyl-2-aminopropane salts in relation to its toxicity in animals and to ascertain its ability to counteract the depression of barbitol hypnoses. Various other types of experiments were performed.

At about this time it was reported that ephedrine had some slightly beneficial effect in the treatment of narcolepsy. Alles induced his co-worker at the University of California Medical School to make a study of the effect of his compound in the disease of narcolepsy. It was found that the 1-phenyl-2-aminopropane salt in this condition had therapeutic advantages far exceeding that which could be demonstrated by ephedrine salts.

From this course of experimentation Alles concluded that he had discovered a useful therapeutic compound having effects similar to ephedrine with regard to its action upon the peripheral sympathetic mechanism and the central nervous system.

***983** The file wrapper discloses that on August 29, 1930, Alles applied for the patent.

On April 18, 1931 the Examiner rejected all of his claims on the basis of two method patents (Buckner 700670, May 20, 1902, and Cole 1,378,939, May 24, 1921) and the Edeleano article in the Berichte der Deutschen Chemischen Gesellschaft.

On September 18, 1931, Alles amended his application by cancelling all of the method claims and certain words and phrases and inserting other words and phrases. This apparently satisfied the Patent Office, for on April 19, 1932, he was advised that his application would be allowed with two claims. On September 27, 1932, his patent with the two claims was allowed.

On August 29, 1934, there was recorded in the Patent Office the receipt of Alles' disclaimer.

Description and Claims

It is the contention of defendants that Alles failed to "particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery" pursuant to the provisions of the statute governing applications for and issue of patents. 35 U.S.C.A. § 33.

The claims, when read in the light of the specifications in order to determine their meaning, lead to the obvious conclusion that Alles claims the sulfate and the hydrochloride of 1-phenyl-2-aminopropane as a new composition of matter useful for therapeutic purposes. The therapeutic purposes are further explained in the specifications by the description that the salts of the base "are physiologically active and produce effects in animals and man similar to the effect of the salts of ephedrine."

A consideration of the contention of defendants must be directed to the meaning and descriptive quality of the words "physiologically active and produces effects in animals and man similar to the effects of salts of ephedrine," as applied to a new composition of matter useful for therapeutic purposes.

Although it is difficult to dismiss from one's thoughts the present-day knowledge of the effects and uses of amphetamine sulfate and all that has been learned about the drug since Alles' application for a patent, it must be done in order to equitably determine whether Alles sufficiently described his discovery in 1930 to come within the requirements of the patent law.

The discovery lies in the field of chemistry and therapeutics, more specifically in the field of compounds that act upon the central and sympathetic nervous systems of animals and man. The closest allied field known to the art in 1930 was that field in which compounds described as sympathomimetic amines were classified. Ephedrine was considered at that time to be one of those compounds. However, despite its effectiveness as a substance exhibiting sympathomimetic activity, it was the only drug in this

field possessing the capacity to affect the central nervous system. In this respect it was not comparable to any other known drug and since the art considered these effects undesirable, no emphasis was placed upon these characteristics of the drug.

A comparison of the sympathomimetic and central activity of ephedrine and amphetamine sulfate results in the conclusion that they are similar insofar as sympathomimetic action is concerned and both drugs possess a like degree of potency or intensity. With reference to action upon the central nervous system they are likewise similar, except that with respect to potency or intensity the action of amphetamine sulfate is considerably stronger than that of ephedrine.

Prior to Alles' discovery there existed no drug capable of having the central nervous effect of amphetamine sulfate. Initially, it was used to achieve the same effects therapeutically as ephedrine, only in greater intensity.

Amphetamine sulfate was found to be decidedly superior to ephedrine in its action upon the central nervous system when used for therapeutic purposes, such as counteracting the effects of barbitol which depresses the central nervous system, in narcolepsy, in post-encephalitic parkinsonism, in producing mood, in decreasing the appetite, in obtaining the effect of wakefulness, and in alleviating fatigue and similar states where the central nervous system stimulant effect is the primary activity. With varying degree ephedrine had been used prior to the introduction of amphetamine sulfate for each of these therapeutic purposes. Therefore, ephedrine had been completely replaced by amphetamine sulfate wherever it had been used for central stimulation. The two drugs, as far as sympathetic effects are concerned, are similar. Even as to these sympathetic effects, in many respects and ***984** for many uses, amphetamine sulfate had been found to be more effective and superior.

It should be noted that amphetamine sulfate has the same high sympathetic effect of ephedrine along with a central effect produced with small dosage. In order to produce a central effect with ephedrine a large dose must be administered, which invariably results in a pronounced peripheral effect. The peripheral effect, so magnified, may be harmful to the patient to such an extent as to outweigh any advantages of the central effect. However, ephedrine, prior to the advent of amphetamine sulfate, was used for its central effects although cautiously. The same symptoms of anxiety complex (central effect) often produced by ephedrine could be obtained by large doses of amphetamine sulfate. Qualitatively the effects of both drugs are similar. Quantitatively, the effects are different. There are certain dissimilarities, such as the inability of ephedrine to produce warmth, well-being or a euphoric effect. Thus far we have considered the effects of both drugs on man. The effects of the drugs on animals are even more similar in so far as they are ascertainable.

In 1930, amphetamine sulfate was used as a substitute for the salts of ephedrine for the reason that it produced the effect of the salts with greater intensity. Its capacity to produce these similar effects resulted in its use for practically the same therapeutic purposes as the salts of ephedrine, or to use the phrase of an expert witness, it was used for its "ephedrinelike" action. Alles intended to claim those effects that were similar to the salts of ephedrine. At that time the definition of the salts of ephedrine in contradistinction to the definition of the salts of adrenaline, the only other compound close to it in effect, meant effects upon the sympathetic *and* central nervous systems. His description of his discovery was based upon the art at that time. Alles then had no better way to describe his discovery to those skilled in the art in 1930. There was no confusion in the minds of skilled chemists, doctors or pharmacologists of the effect of the salts of ephedrine, and when told that a particular composition is physiologically active and has similar effects in animals and man, they would know the

exact effects of such compound. Therefore, the objection by the defendants inadequacy in description directed towards the claims originally made by Alles, fails.

Defendants submit that if the Alles' patent is declared valid the public will be excluded from the use of amphetamine sulfate for effects which are not similar to the "practical" effects of the salts of ephedrine. The defendants persist in making comparisons between the effects of amphetamine sulfate and the "practical" effect of the salts of ephedrine. They say that the salts of ephedrine have no "practical" effect in obesity and for other clinical uses, and hence there is no comparison between amphetamine sulfate and the "practical" effect of the salts of ephedrine.

We cannot agree with this position because we feel that the qualitative effects of amphetamine sulfate and the salts of ephedrine are similar. We agree that the central effect of the salts of ephedrine are quantitatively lacking in intensity compared with the effects of amphetamine sulfate. We also agree that salts of ephedrine for "practical" purposes are not as useful as amphetamine sulfate. Consequently the use of the compound is governed by the quantity of the qualitative effect desired in so far as effects are concerned.

Our considerations are based upon the similarity of the qualitative effect in both compounds in the light of their therapeutic action as they have to do with sympathetic and central effects of the nervous system.

We cannot presently concern ourselves with future discoveries of uses of this compound in fields unrelated to the effects it may have other than on the central and sympathetic nervous systems. We are now concerned only with what Alles has claimed as a new substance for certain therapeutic purposes. If other uses should develop for the compound and patents are claimed for

those uses, the issue will then concern an old compound for an allegedly new use.

Disclaimer

The defendants attack the propriety of the disclaimer under the patent laws on the theory that it changed the nature of the claimed invention. They point out that if the disclaimer is improper it voids the entire patent and nothing remains to be adjudicated with reference to the charge of patent infringement in this action.

In support of this proposition the cases of Milcor Steel Co. v. George A. Fuller ***985** Co., 2 Cir., 122 F.2d 292, affirmed 316 U.S. 143, 62 S. Ct. 969, 86 L. Ed. 1332, and Altoona Theatres v. Tri-Ergon Corporation, 294 U.S. 477, 55 S. Ct. 455, 79 L. Ed. 1005, are submitted. The disclaimer involved in each of these cases was considered improper because it added a new element to the original claim of invention rather than limiting the original claim to that part of it which the patentee claimed as his invention. The patent in the Milcor case related to the construction of a wall which included a base member, a ceiling member, upstanding wall supports vertically movable and the means operative to prevent tilting. The inventor disclaimed any scope for these claims except, as to the ceiling member, a "vertical depending perforated flange, one side of which is overlapped by metal lathe" [122 F.2d 293] and, as to the base member, "composed of a longitudinal strip having recesses to receive the lower ends of the webs of channel wall supports, the flanges of the channel wall supports overlapping the base member adjacent the recesses." The court concluded that the limitation of the original claims by the disclaimer to the construction of the members was an addition to the original claim. The novelty consisted of the combination set out in the claims and the abandonment of a part of each claim resulted in

transforming the combination into a new and different combination which the disclaimer statute could not be invoked to justify.

Similarly, in the Altoona case, claims for a method of translating sound or similar vibrations to or from a film record and an apparatus for reproducing sound from vibrations recorded on a film by the use of light varied in accordance with the sound, were disclaimed so as to cover the combination only when used in conjunction with a flywheel. The court found that the flywheel was added as a new element to each of the combinations described in the claim so as to transform the original combination into a new and different combination.

These cases draw a distinction between a disclaimer which limits the original claim, in that the invention claimed is a part of the original combination or composition which then can be severed from the whole without altering the combination which is claimed as an invention, and a disclaimer which although it narrows the original claim, in so doing adds an additional or new element to the original claim so as to alter or completely change a part of the original combination or composition which destroys its identity. The latter (not a valid disclaimer) is illustrated in the aforementioned cases by the addition of the flange to the ceiling and to the base members of the wall and the addition of the flywheel to the film record.

In effect, the invention claimed originally and that claimed after the disclaimer must be the same invention except that it may be limited or diminished in scope and/or its parts particularized as long as the combination or composition is not altered. The decisions sustaining disclaimers as valid bear out this proposition. It is illustrated in the case of Johnson Laboratories, Inc., v. Meissner Mfg. Co., 7 Cir., 98 F.2d 937, where to a claim for a compressed comminuted magnetic material with individual insulated particles, a disclaimer was added including the specifications that the particles should be of a particular minute size and of a specified

"apparent permeability," which disclaimer was sustained by the court, no new elements having been added and the residue including enough to support the claim. It was stated in the opinion:

"* * * Obviously, if a disclaimer purports to widen the invention and to make the claim broader, it is invalid. It cannot be used to change the character of the invention or to make a new patent. But if the reasonable intendment of the specifications is to disclose that the part disclaimed is separable from that retained, then the part disclaimed, if no new element is added, will not affect the residue provided the latter includes enough to support the claim of invention. A disclaimer is proper when the patentee has been wrong in asserting that the whole claim is new but right as to a part which constitutes invention and which does not depend upon what he disclaims." 98 F.2d at pages 944, 945.

Therefore, in the case of Cincinnati Rubber Mfg. Co. v. Stowe-Woodward, Inc., 6 Cir., 111 F.2d 239, a disclaimer of the words, "and elsewhere," which had the effect of confining a patent relating to rolls in paper making to paper making machines, was declared valid, for it limited the claim by the exclusion of a part to a field which it might in its original form have covered. The case of Byrne Mfg. Co. v. American Flange & Manufacturing Co., 6 Cir., 87 F.2d 783, cited by the court in the Cincinnati ***986** case, was another instance where the validity of a disclaimer was sustained as not adding a new element. The original claim in that case related to the method of applying bushing to metal containers. Certain annular bushings and certain methods of applying bung rings to the metal containers were disclaimed and the disclaimer did not constitute a new element.

In the instant case the original claims are (1) a salt of 1-phenyl-2-aminopropane and (2) the hydrochloride of 1-phenyl-2-aminopropane as new compositions of matter. These claims are disclaimed to the extent that they are in excess of acting as a physiologically active therapeutic agent

capable of producing effects in animals and man similar to the effect of salts of ephedrine. The composition to produce this effect is stated in the disclaimer to be a salt of 1-phenyl-2-aminopropane and the hydrochloride of 1-phenyl-2-aminopropane, which are the identical compositions originally claimed. The limitation or restriction of the disclaimer adds no new or additional element to the original claim of composition nor does it alter the original claim of composition so as to destroy its identity. The same invention is claimed.

The authority for filing a disclaimer is found in the following statute:

"Whenever, through inadvertence, accident, or mistake, and without any fraudulent or deceptive intention, a patentee has claimed more than that of which he was the original or first inventor or discoverer, his patent shall be valid for all that part which is truly and justly his own, provided the same is a material or substantial part of the thing patented; * * *." 35 U.S. C.A. § 65.

As originally filed, Alles' claims were for new compositions of matter. Literally as such they were meaningless, except to name chemical compositions. As mentioned heretofore, in the specifications of the patent, Alles set forth its purposes and further particularized those purposes. These references in the specifications must be read together with the claims of the patent to determine the real meaning of the claims, since nothing to which reference has been made in the specifications enlarges the claims.

"The claims of a patent are always to be read or interpreted in the light of its specifications, Hogg v. Emerson, 11 How. 587, 13 L. Ed. 824; Carnegie Steel Co. v. Cambria Iron Co., 185 U.S. 403, 22 S. Ct. 698, 46 L. Ed. 968; Smith v. Snow, 294 U.S. 1, 55 S. Ct. 279, 79 L. Ed. 721; * * *." Schriber Co. v. Cleveland Trust Co., 311 U.S. 211, at page 217, 312 U.S. 654, 61 S. Ct. 235, at page 238, 85 L. Ed. 132.

See, also, numerous cases following 35 U.S.C.A. § 33, notes 143-148, inclusive.

When the claims of this patent are read with the specifications, they plainly indicate that the compounds are useful therapeutically as physiologically active in producing effects in animals and man similar to the effect of the salts of ephedrine.

The disclaimer added nothing to the claims of the original patent and it may be said that it did not diminish the claims of the original patent when read in the light of the specifications. It indicated that the exact claims made by the patentee by disclaiming all in excess of "a physiologically active therapeutic agent capable of producing effects in animals and man similar to the effect of salts of ephedrine * * *." At most, the disclaimer left the claims of the patent where they were, but did not invalidate them.

A further argument advanced by the defendants in support of their motion proceeds on the theory that the admissions of the plaintiff invalidate the original claim of invention leaving nothing to adjudicate with reference to the patent. The defendants contend that "the presumed prima facie validity of the present patent is entirely overcome by the fact that the disclaimer admits that the subject matter originally claimed was not the invention of Gordon A. Alles and that it was necessary to change the claims after the patent issued in order to distinguish what Gordon A. Alles claimed to have invented from what was admittedly old." It is argued that the disclaimer rewrote the claims and what was originally alleged to be a new composition is now claimed to be a new use for an admittedly old composition which is not recognized as a patent under the law.

The defendants point to the plaintiff's answer to defendants' request for admission under Rule 36 of the Federal Rules of Civil Procedure, 28 U.S.C.A. following section 723c, in which

"* * * plaintiff admits that on August 29, 1934, Gordon A. Alles knew that the subjects-matter:

***987** "`1. As a new composition of matter, a salt of 1-phenyl-2-aminopropane.

"`2. As a new composition of matter, the hydrochloride of 1-phenyl-2-aminopropane.'

respectively, included that of which he was not the inventor and avers that said Gordon A. Alles was the first inventor of a salt of 1-phenyl-2-aminopropane and of the hydrochloride of 1-phenyl-2-aminopropane, respectively, as physiologically active therapeutic agents capable of producing effects in animals and man similar to the effect of salts of ephedrine."

In brief, the defendants urge that as a result of the disclaimer and the admissions made by plaintiff, it is relegated to the position of claiming a new use for an old composition and that such a claim cannot be the subject of a valid patent.

A disclaimer does not have the effect of conceding that which is disclaimed is in the prior art nor does a disclaimer admit that the patent would be void in its absence. Payne Furnace & Supply Co. v. Williams-Wallace Co., 9 Cir., 117 F.2d 823; United Chromium v. International Silver Co., 2 Cir., 60 F.2d 913; N. O. Nelson Mfg. Co. v. F. E. Myers & Bro. Co., 6 Cir., 56 F.2d 512; Permutit Co. v. Wadham, 6 Cir., 13 F.2d 454.

The admissions of the plaintiff, under Rule 36, standing alone, concede only that the patentee was not the first inventor of the base of the composition and assert that he was the first inventor of a salt of 1-phenyl-2-aminopropane and the hydrochloride of 1-phenyl-2-aminopropane, respectively, physiologically active therapeutic agents capable of producing

effects in animals and man similar to the effect of salts of ephedrine. This statement does not imply, without further proof, that the patent, as disclaimed, is invalid.

Validity of the Patent

A summary of the prior art at the time of Alles' discovery reveals that the base 1-phenyl-2-aminopropane was produced by Edeleano in 1887; that this base was listed as produced by Edeleano in Beilstein's encyclopedia of organic compounds in 1896 and the substantially identical listing appeared in the 1929 edition; that the substance known as adrenaline or epinephrine was chemically synthesized and its effect on the sympathetic nervous system studied and that this work was considered to be in the field of sympathomimetic amines after the experiments of Barger and Dale in 1910; that Percy May summarized this work in 1921 in a chapter of his book dealing with adrenaline and other derivatives of ethylamine; that ephedrine was introduced by Chen and Schmidt in 1924 as a drug which was therapeutically useful for its effects upon the sympathetic nervous system as well as effects upon the central nervous system; that Jones and Wallis experimented with the hydrochloride of 1-phenyl-2-aminopropane in 1926 with questionable results; that Hey referred to Edeleano and Jones and Wallis respectively as having obtained the base and hydrochloride of the d-form of b-phenylisopropylamine.

Throughout the entire period during which the field of sympathomimetic amines was explored prior to Alles' discovery, the investigation and experimentation limited itself exclusively to the effects upon the peripheral or sympathetic nervous system. Any effect upon the central nervous system was considered to be for the most part disadvantageous and undesirable.

The articles dealing with chemical analyses exclusively are those of Edeleano, Jones and Wallis and Hey. As has been said Edeleano synthesized the base of amphetamine sulfate and provided the art with the formula thereof. Jones and Wallis, like Edeleano, engaged in chemical testing alone and attached no use to the results of their experiments. The Hey publication was a reference to the works of Jones and Wallis. Those facts did not preclude a patent for the discovery of a derivative thereof for a therapeutic use.

In the case of Kuehmsted v. Farbenfabriken of Elberfeld Co., 7 Cir., 179 F. 701, at page 705, certiorari denied 220 U.S. 622, 31 S. Ct. 724, 55 L. Ed. 613, the court said:

"Hoffmann has produced a medicine indisputably beneficial to mankind something new in a useful art, such as our patent policy was intended to promote. Kraut and his contemporaries, on the other hand, had produced only, at best, a chemical compound in an impure state. And it makes no difference, so far as patentability is concerned, that the medicine thus produced is lifted out of a mass that contained, chemically, the compound; for, though the difference between Hoffmann and Kraut be one of purification only strictly marking the line, however, where the one is therapeutically available and the others ***988** were therapeutically unavailable patentability would follow. In the one case the mass is made to yield something to the useful arts; in the other case what is yielded is chiefly interesting as a fact in chemical learning. Merrill v. Yeomans, 94 U.S. [568], 569, 24 L. Ed. 235; Badische v. Kalle, 2 Cir., 104 F. 802, 44 C.C.A. 201; Badische [Anilin & Soda Fabrik] v. [A.] Klipstein [& Co.], C.C., 125 F. 543."

The court said in the case of Eastman Kodak Co. v. Coe, D. C., 40 F.Supp. 891:

"I think that the production of a new chemical compound, even though some one has stated that such a compound may exist is an invention within the meaning of the patent laws and that the plaintiff is entitled to the relief sought." 40 F.Supp. at page 891.

The articles dealing with effect as well as chemical analysis, as distinguished from those dealing with chemical analysis exclusively, are those written by Barger and Dale, Percy, May, and Chen and Schmidt.

Barger and Dale's experiments on animals with the central nervous system destroyed is evidence that their attention was not directed towards effects upon that system. Barger and Dale experimented with compounds having chemical structures similar to adrenaline or epinephrine (and close to that of amphetamine sulfate), but with a view towards reporting optimum sympathomimetic action, or action similar to the effects of adrenaline or epinephrine.

Percy May's review of the information gathered in the art incorporated bodily the work of Barger and Dale in this field. Nowhere in either of these publications does it appear that the art was even remotely interested in compounds which would produce central effect or that any one ever discovered such a compound, much less that compounds closely resembling in chemical structure those being studied for sympathomimetic action existed or could be produced which would possess the capacity to achieve central effect. The art was not sufficiently advanced at the time of these publications to recognize the possibilities of central effect in medicine. Efforts to remove these effects were made continuously. Indeed, the chemical structure of compounds exhibiting central effect were not known prior to Alles' work in the field. Even in the case of ephedrine, considered by Chen and Schmidt, that part of its chemical structure responsible for the central stimulating effect of the drug was unexplainable and unknown. However, from Barger and Dale to the time of Alles it was considered that

the maximum activity occurred in compounds of significantly useful sympathomimetic amines, the structures of which consisted of a benzene ring with a side chain of two carbon atoms and the amino group attached to the second carbon atom. An infinite number of compounds could be made on this structure. In ephedrine we have, for the first time, in a drug belonging to the field of sympathomimetic amines, a distinct stimulation of the central nervous system when given in large doses or in ordinary doses to sensitive individuals. This effect was considered incompatible with its action on the sympathetic system.

Some of the conventional rules governing patent law are succinctly stated in the case of Strong-Scott Mfg. Co. v. Weller, 8 Cir., 112 F.2d 389, at page 394, where the court said:

"The issuance of a patent is prima facie evidence of both novelty and utility. When one attacks a patent, he must make good his attack with reasonable clearness. The burden of proof is upon him, and every reasonable doubt will be resolved against him. While commercial success cannot convert mechanical skill into invention, it may, in doubtful cases, constitute evidence of invention. Simplicity alone cannot be relied upon as indicating that an improvement is the result of mechanical skill rather than inventive genius. If the description in the patent is such that one skilled in the art can follow it and produce the result which the patent claims, the description is sufficiently certain. These rules are sustained by an abundance of authority, as pointed out in Donner v. Sheer Pharmacal Corporation, 8 Cir., 64 F.2d 217, 220-222."

In the instant case there is nothing in the file wrapper or in the evidence to deny to the patent the presumption of validity which arises on its issuance.

We have heretofore referred to evidence given by experts at the trial without attributing specific portions of it to specific witnesses. It appears to be

sufficient to say that the plaintiff produced the testimony of Dr. Carl F. Schmidt, collaborator with Dr. K. K. Chen in the introduction of ephedrine; Dr. Abraham Myerson, authority in the field of neuropsychiatry; Dr. Edwin C. Reifenstein, experienced as a physician and research investigator. The defendants ***989** called Dr. Harry Gold, physician and pharmacologist of experience and standing.

All of these witnesses were inclined to inspire confidence by their statements. They were of a common opinion, in which even Dr. Gold agreed substantially, on the general effects of ephedrine and amphetamine sulfate in the fields of pharmacology and medicine.

Other witnesses who testified on behalf of the plaintiff on the patent side of the case were Doctors Gordon A. Alles and George H. Connitt and for the defendants Dr. Samuel W. Kalb, Charles L. Morris and Philip Sadtler.

Alles, as plaintiff's assignor, and Morris, as one of the defendants, of course, have opposing interests in the outcome of the litigation. Connitt is an employee of the plaintiff, while Sadtler has a financial interest and concern in the success of the defendants' position. Dr. Kalb, a large user of amphetamine sulfate in his extensive practice in obesity, conceded that he could buy the drug much cheaper from the defendants than from the plaintiff, and to such extent was also an interested witness.

We are convinced of the credibility of the testimony offered by the plaintiff and that the weight of the evidence, insofar as its witnesses as mentioned above were concerned, is with it where they were a factor in sustaining the burden of proof by a preponderance of the evidence.

To the extent that the burden of proof falls upon the defendants as the attackers of the patent, we are convinced that they have failed to sustain it, particularly in the light that all reasonable doubts should be resolved against them.

There is no dispute as to the successful commercial exploitation of the patent nor that one skilled in the art could follow the instructions of the Alles' patent and obtain the result.

From the evidence adduced at the trial it appears that up to 1924, when ephedrine was introduced by Chen and Schmidt, no substance was known to have exhibited any marked effect upon the central nervous system. Even this addition to the art stimulated no apparent interest in the study of central nervous effects with respect to compounds of this type. Alles was the first to explore the possibilities leading to a compound which produced a marked central effect. In the construction of his compound Alles was the first to use a benzene ring with a side chain of three carbon atoms with the amino group attached to the middle carbon atom, a combination completely overlooked in the work of Barger and Dale in their test for optimum activity. He was the first to consider that a drug which produced such an effect would be of therapeutic use, and it is not material that he might not have realized the far-reaching results that eventually came about. The thought and experimentation involved in this work were original with Alles.

The art up to Alles' work did not serve as a basis for the discovery of Alles that the compound amphetamine sulfate would have central effects.

It eventually developed that the discovery of the utility of amphetamine sulfate has been recognized as an outstanding contribution to science and a great benefit to humanity. Some of the principal clinical uses of the drug which are known today follow: In narcolepsy, for the purpose of counteracting barbiturate poisoning, for hang-over produced by alcohol, for mood, neurosis and the nervous diseases of the mentally sick, in post-encephaletic Parkinson's disease, to control appetite in obesity, for use in emergency where alertness and similar reactions are desired, for shock by the lifting of blood pressure, in epilepsy, in connection with the care of problem children, in X-ray work to relax the spasm and to relax the gastro-

intestinal and genito-urinary tracts. It may be noted that all these uses are concerned with central effects, except the last two relating to the effects of relaxation which are sympathetic effects.

Its many uses have made it possible to cure ills and save life. It has opened up a new field of medicine. The possibilities of the use of this drug in the therapeutic care of neuropsychiatric disorders are inexhaustible. It has replaced drugs which were formerly used for the treatment of human ills. It is the first time that a drug has been found which has the capacity to successfully affect mood, temperament and emotion, an unexplored field of medicine. It has also opened up a vista of chemical research which may lead to new and more efficient compositions having the capacity to produce effects upon the central nervous system.

The present case has many distinctions over the innumerably reported cases. Alles as a research investigator was embarked on a mission to find a chemical compound ***990** that would be as helpful as ephedrine but in more abundance. In this quest he made a compound which produced the qualitative results of ephedrine but in varying quantitativeness, particularly as regards the central effects of ephedrine. This very quantitativeness of effect was new and surprising to Alles. He came upon it not by means of routineering in which one step prepared the way for the next but rather by spontaneous trials and attempts. He produced a compound that was not simply an exercise in chemistry but one that had definite therapeutic effects relatively qualitative in action to that of ephedrine, and in his patent he sought to tell the world of that which he had discovered.

This was not a case of knowing in advance what result would be achieved. This was not a case of searching for the missing element which would accomplish that result nor a case where an improvement over the present state of the art was being sought to make it more practical or cheaper. Neither did Alles' work fall into the class of cases described by the court in

the case of Potts v. Coe, 78 U.S.App.D.C. 297, 140 F.2d 470, where the court related the practice of mammoth corporations to engage many of their employees in research toward a given patent objective. Alles worked alone or was assisted by colleagues, the usual manner in which chemists conduct their experiments. While he assigned his patent to the plaintiff, a relatively large pharmaceutical house, it is but one of a number of pharmaceutical houses and not a patent owner having the almost complete monopoly of patents as attributed to the patent holder in the Potts case.[1]

***991** Congress is aware of the burning controversies that rage over the alleged inadequacies and inefficiencies of our antiquated patent law. It is common knowledge that its committees as well as other governmental agencies have been and are ***992** investigating practices in the field of patents with a view to formulating recommendations for substantial revisions and changes to be enacted in the patent system.

It remains for the lawmaking body to courageously and intelligently take up its responsibilities to amend and clarify and synchronize the patent system with the times and the technological age in which we live and not for this court to judicially legislate its individual ideas of the appropriate social and economic practices that should prevail in the light of the modern age as substitutes for stabilized regulation by statute.

We believe we have shown that neither Edeleano, nor Jones and Wallis anticipated Alles by their publications. However, if we should concede that Edeleano demonstrated these salts of the base or that Barger and Dale accurately disclosed the optimum activity of this chemical structure or that Jones and Wallis produced this hydrochloride of the base we would still regard Alles as entitled to the protection of the patent law. None of the scientists who worked before him attached to their work any of the elements or factors that would give it status as having inventiveness, for none connected it with its effects upon the human organism. It was here that Alles

departed from the step by step testing of chemicals and by his experimentation struck the spark of genius when he discovered the therapeutic use which the effect of his compound would have upon the human central nervous system.

It is easy to say, looking at the results of Alles' findings through hindsight, that any skilled chemist could arrive at the composition which is the subject of the patent claims. To the extent that a skilled chemist might reproduce the base by the method described by Edeleano and convert that base into a salt by a method known to the art, that statement is correct, but the fact is, that although these methods had been available to the art for almost a half century, no one reproduced the base or produced the salt thereof for any therapeutic use whatsoever, for the reasons that no therapeutic use had ever been known for the composition and that the central effects of compounds of similar structure had been considered undesirable. No one exercised any original thought by which a possible use for the composition could be found. The original thought and experimentation were added to the art by Alles. No use was ever advanced or suggested for the base of the compound produced by Edeleano or for the use of compounds of similar chemical structure in the art prior to the contribution of Alles. He did not find a new use for an old known composition, but for the first time he found a salt of a composition and the effects of it. The base of the composition was known and the salt was obtainable by a known method, although there is no evidence to show that it was ever produced for, or that it was ever suspected of, therapeutic use.

Although not conclusively proven, there is some evidence to believe one skilled in the field of sympathomimetic amines might forecast from the chemical structure of a compound whether it possessed sympathomimetic activity, but even that prediction is admittedly a guess. When we speak of sympathomimetic activity we speak of the exhibition of such activity to a certain degree. In order to find that degree, experimentation is essential.

Furthermore, whether the compound exhibiting the sympathomimetic activity upon experimentation, whatever its degree, may be used therapeutically, requires further experimentation. The chemical structure indicates no more than assumption of its sympathomimetic activity to one skilled in the art, but the type of action, the oral effectiveness of the compound, the duration of action, the undesirable side effects, and the effects it might have on the central nervous system considered undesirable prior to Alles are some of the factors that had to be determined before any use could be found for the compound.

There is no evidence to show that from chemical structure alone a skilled chemist could assume or predict that a compound so constructed would have any effect upon the central nervous system. Not only does the evidence fail to show that any one prior to Alles considered a use for amphetamine sulfate, or a compound of similar chemical structure, but it does not disclose that any one ever considered the therapeutic use of any drug exhibiting effects upon the central nervous system. This experimentation was accomplished by Alles. The results were overwhelmingly successful. His reports based upon these experiments furnished the art with evidence of the accomplished effects and therapeutic uses of amphetamine sulfate so that it might be successfully used with beneficial results.

***993** In order to arrive at findings based upon originality and novelty to a degree that may be termed invention in a legal sense, the only method available in the fields of chemistry and therapeutics is experimentation. Experimentation to find the new in composition must be, of necessity, with known elements.

Experimentation in chemistry upon compositions from the standpoint of therapeutics must reflect effect. The desire to create a certain effect because one believes that effect can be therapeutically useful or the curiosity to discover whether an effect would be a therapeutically valuable one, would

impel one to conduct such experiments. It is the effect it produces which brings the composition up to the high standard of invention in therapeutics. Without the useful effect, the composition, although new, is of no value, except possibly academically, and certainly unpatentable. The field of chemistry is filled with formulas and compositions for which no use has yet been found. Are we to discourage the finding of beneficial uses of known formulas and compositions by concluding that the publication of the laboratory method of preparing compositions without declaration of purposes precludes any further findings with regard to that substance from being the subject of a patent? If we were to so conclude, we should deprive the protection of our patent law to the fields of chemistry and therapeutics, fields in which great advances have been made towards the relief of the suffering of mankind and aiding man to a longer and a better life. It is our conclusion that a salt of 1-phenyl-2-aminopropane was produced for the first time by Alles as a physiologically active therapeutic agent capable of producing effects in animals and man similar to the effect of salts of ephedrine and that what he disclosed is a new and useful composition of matter not known or used as such by others in this country, and not patented or described in any printed publication in this or any foreign country before his discovery thereof and which is of inventive character and patentable.

Infringement

The defendants are charged with the infringement of claim 1 of the patent involving salts of 1-phenyl-2-aminopropane. No evidence is offered to show any infringement of claim 2 of the patent involving the hydrochloride of 1-phenyl-2-aminopropane. The hydrochloride is involved only as it is concerned in the prior art.

The testimony shows that defendants furnished druggists with 5- and 10-milligram tablets of amphetamine sulfate with which to fill doctors' prescriptions for the drug. Other tablets were likewise furnished which contained amphetamine sulfate in combination with other drugs, such as thyroid and phenobarbital. The defendants also furnished tablets to doctors so that they could be dispensed directly to patients.

The defendants concede that they manufactured and sold tablets of amphetamine sulfate, but that the use to which the tablets was put was controlled by the physician who prescribed them and the patient who took them. They submit that unless the patient used them to obtain the effects similar to the effect of the salts of ephedrine, there could be no infringement charged to them, even by way of contribution. They differentiate between the use of amphetamine sulfate and the salts of ephedrine because they say that the results or effects obtained by the use of the latter would not be satisfactory for the purposes desired for which the former only would serve. In obesity, in the treatment of narcolepsy, alcoholism and other uses, their witnesses testified that the effects of the salts of ephedrine were undesirable, whereas the effects of amphetamine sulfate were desired and used.

The defendants further contend that it is almost impossible to ascertain the extent, if any, of alleged infringement because it would be necessary to follow the use of the amphetamine sulfate to the particular patient to determine for what purpose it had been prescribed and what effects were obtained and whether those effects were similar to the effect of the salts of ephedrine.

As we have already noted the Alles' patent covered a salt of 1-phenyl-2-aminopropane as a therapeutic agent capable of producing effects similar to the effect of salts of ephedrine. The testimony shows that amphetamine sulfate produces effects upon the sympathetic and central nervous systems. The salts of ephedrine also produce effects on the same systems. The fact

that the latter does not produce as much effect on the central nervous system as to give it utility in those conditions where it is desirable to have more intensity of effect ***994** upon the central nervous system does not limit the Alles' patent. That grant extends to the use of 1-phenyl-2-aminopropane as a therapeutic agent whenever it produces effects similar to the effect of salts of ephedrine.

The testimony of the medical witnesses was overwhelming that amphetamine sulfate was used therapeutically at this time for its effects on the sympathetic and central nervous systems and largely for those upon the central nervous system. No other therapeutic purpose was shown to be known for the drug. The defendants manufactured and sold amphetamine sulfate for therapeutic or medicinal purposes to produce effects similar to those produced by the salts of ephedrine. They cannot escape liability for infringement by hiding behind the assertion that the use to which the drug was put by druggists, doctors and patients could not bind them. They enabled all others to violate the rights protected by the patent for they knew that the purchase of the compound was solely for its known effects.

In this they infringed the Letters Patent No. 1,879,003 assigned by the patentee Alles to the plaintiff.

Part IIUnfair Competition

A. Plaintiff's Charge of Unfair Competition

Plaintiff is an old established and wellknown pharmaceutical house in Philadelphia. It has marketed amphetamine sulfate in tablet form since December of 1935. Tablets containing 5 milligrams and 10 milligrams of the drug are sold in packages of 25 and 250 tablets, each package bearing a label

which includes its trademark "Benzedrine" or "Benzedrine Sulfate Tablets", and the generic chemical name of the drug (benzylmethyl carbonamine sulfate was used as a generic name up to 1938 and thereafter amphetamine sulfate).

The price of the plaintiff's product for the 10-milligram tablets since January 1, 1939, has been as follows: $8 per dozen for packages of 25 tablets each and $5.65 for each package of 250 tablets.

The 10-milligram amphetamine sulfate tablet produced by plaintiff since September of 1936 may be described as follows: A small white, round tablet with a diameter roughly of about half the diameter of a nickel and a little less than twice the thickness of the same coin. The top surface is crossed by two furrows or grooves which bisect each other at right angles at the center. The top surface is level and rimmed with a small bevel, and the crossed furrows or grooves are set to a depth slightly lower than the lowest edge of the bevel. As one looks at the top surface he finds it divided into four equal wedge-shaped sections. Since the furrows or grooves are V-shaped, they form a distinctive design at the point where they converge at the center of the top of the tablet. The side walls are smooth and seem glossy. The bottom surface of the tablet is a little concave, making it appear as if there were a narrow border around the bottom.

In 1940 the plaintiff put upon the market a smaller amphetamine sulfate white tablet containing 5 milligrams, the top surface of each being crossed by a single V-shaped furrow or groove which runs from edge to edge across its center. Roughly the diameter of this tablet is about half the diameter of a dime and slightly more than twice as thick as the same coin. Its top surface is flat and rimmed with a small bevel, similar to its 10-milligram counterpart. The V-shaped groove which runs from edge to edge across the center of the surface is set to a depth of a little lower than the lowest line of the bevel. The bottom surface of this tablet is also slightly concave.

The plaintiff sells the drug at wholesale to hospitals, jobbers and retail outlets. The patient obtains the drug from the doctor or from the pharmacist only upon presentation of a doctor's prescription.

Since September of 1936 the plaintiff has exploited the distribution of the drug by advertising, educational campaigns, pictorial displays, and acquainting the medical profession with the usefulness of the preparation by distributing sample tablets and reprints of medical papers and articles. It took the customary means of displaying the article at medical conventions and addressing the interested professions by letter and otherwise calling attention to the compound.

Plaintiff states that it sent its literature to approximately 100,000 doctors in the United States. In each year since September 1936 it claims to have circularized that number, or more, of physicians and to have distributed over 2,000,000 samples since that date.

The sales of the product over the period of years since its introduction on the market ***995** reached approximately 150,000,000 tablets in number or $2,800,000 in amount for the 10-milligram amphetamine sulfate tablets. The plaintiff also claims to have distributed the tablet to the consumer through some 7,500,000 physicians' prescriptions, besides which the United States and British governments have bought plaintiff's product in large quantities.

Since 1935 plaintiff claims to have spent $276,750 on research.

The reception accorded the introduction of the product is evidenced by the large number of articles and papers written and published by physicians and pharmacologists with reference to the effects of the compound.

Evidence of doctors and druggists was introduced at the trial that they recognized the tablet as amphetamine sulfate, known by its trade name of Benzedrine and as the product of the plaintiff, as a result of the widely

circulated information and distribution of the product by the plaintiff. They testified that they identified the tablet by its unique and distinctive appearance.

Charles L. Morris, one of the defendants, a graduate pharmacist, was proprietor of a drugstore in Roselle, New Jersey. In the fall of 1936 he entered the employ of E. R. Squibb & Sons, a competitor of the plaintiff, as a salesman. In October of 1941 he formed the defendant corporation, Clark & Clark, while still in the employ of Squibb. Together with his wife he has always owned a controlling interest in Clark & Clark, and recently he acquired all the outstanding stock of the corporation. The name of the company is alleged to have had its origin from the maiden name of his wife. He claims his choice of the corporate name was quite arbitrary with the thought that the corporation might in the future come to be referred to as "C. & C.," as in the instance of other initials which identify large pharmaceutical concerns.

Charles L. Morris is the moving figure among the defendants and provides the active and dominating force that influences the corporate defendant and remaining defendant in the case, his brother, Robert Brinton Morris. When we use the name "Morris" hereinafter, it will be understood that we refer to Charles L. Morris, unless we indicate otherwise.

In October of 1941, the corporation, Clark & Clark, purchased the machinery and equipment of Standard Medical Laboratories, located at 417 Mickle Street, Camden, New Jersey, and established itself at that address. David Olmstead, a pharmaceutical chemist, was connected with said laboratories. He associated himself with Clark & Clark as vice president when that company took over. Robert Brinton Morris was also active with Clark & Clark, which immediately commenced to manufacture amphetamine sulfate tablets. Olmstead had charge of the production of the tablets and Robert Brinton Morris sold them. However, Morris was active in

the sale of these amphetamine sulfate tablets, although at the same time he was still engaged as a salesman for Squibb.

Apparently the first amphetamine sulfate tablets produced by Clark & Clark were made from the punches and dies taken from the Standard Medical Laboratories. These punches had been used for the purpose of making certain eucathesian tablets. This tablet was scored with two lines crossing at the center of its top surface at right angles. The indentation made by these lines formed only thin grooves in the surface of the tablet. It was round, flat and devoid of any ridges or concavities.

One of its first customers was The Lannett Company, jobbers of pharmaceutical supplies in Philadelphia. The negotiations with The Lannett Company were conducted by Morris and his brother, Robert. In December of 1941 negotiations took place between Morris, on behalf of Clark & Clark, and one Cusamano, in New York, which resulted in the production by Clark & Clark of amphetamine sulfate tablets for Cusamano. These tablets were produced from punches and dies which Cusamano provided for the purpose. It was then known to Morris that the tablets Clark & Clark produced for Cusamano and the tablets sold by Cusamano were similar in appearance to the 10-milligram amphetamine sulfate tablets of the plaintiff.

Morris approached Robert Hart, sales manager in charge of the new products and development department of Squibb, his employer. Morris testified that Squibb was looking for a new specialty product and he suggested to Hart the sale of amphetamine sulfate tablets. He also testified that his intention in making the suggestion to Hart was to ascertain whether the plaintiff's patent was valid or not by having Hart procure an advisory opinion from the attorneys of Squibb. Hart is said by Morris to have told him that Squibb did not believe ***996** plaintiff's patent was a valid one, but that it did not intend to go into the amphetamine sulfate tablet market. In addition, Morris stated that, in answer to his questioning of Hart, he was advised that ephedrine-like

compounds make very good specialties in the pharmaceutical business; that amphetamine sulfate was an ephedrine-like drug; and that any one entering this business should be able to make a good profit. It is to be noted that at the time of this discussion Morris was actively engaged in producing and selling amphetamine sulfate tablets through his corporation.

Morris admitted that one of the factors which led to his decision to enter this market was that he knew that plaintiff was marking up its product to such an extent that it was making large profits and concluded that if he went into this field he likewise could profit handsomely.

In the meantime Cusamano in February of 1942 had associated himself with Ben Zirin and Henry Starr in a concern known as Custazin Products, which continued the sale of amphetamine sulfate tablets in the same form under the name of "Custazin."

Prior to April 1942 the employment relationship between Squibb and Morris was severed, and Morris devoted himself entirely to the business of Clark & Clark.

In April of 1942 the present 10-milligram amphetamine sulfate tablet of Clark & Clark was produced after a decided change was made in the form and appearance of the tablet used up to that time. These changes were effected in the shape and form of the tablet by a tool maker in New York, named Johnson. Morris took the punches to Johnson and told him he wanted to produce tablets that would be something between his original amphetamine sulfate tablet and the Cusamano tablet. Johnson used a pantograph, an instrument designed to make accurate copies, to produce the punches for Morris.

The reworked punches produced a tablet strikingly similar to that of the plaintiff. The similarity in appearance between the Clark & Clark tablet and the plaintiff's was brought to the attention of Morris by Olmstead. Morris, in

his testimony, confirmed this and stated that he had ascertained that the punches were producing tablets similar to the plaintiff's, but that he did not particularly care.

Morris employed Benjamin Zirin as a salesman for Clark & Clark in June 1942.

Morris conceded that the business of Clark & Clark was "practically exclusively" in amphetamine sulfate and compounds thereof. He stated that it sold a series of tablets of different colors, known as Clarkotabs, and that 50% of the business of his company was done in the sale of these tablets. The tablets contain various mixtures of amphetamine sulfate, thyroid, phenobarbital and other drugs in different quantities and tablets of three different colors are prescribed for different hours in a single day. He claims that the other 50% of his business was divided equally between the sale of straight 10-milligram amphetamine sulfate tablets and amphetamine sulfate tablets of shape, colors and sizes, different from the plaintiff's tablet.

Clark & Clark's tablets have been sold for as much as $12 per 1000 tablets. Morris attempted to keep the price of his company's tablet at $9.75 per 1000 tablets and stated that he lowered it whenever it was necessary to meet competition and that when it was necessary to lower it that it had been lowered to as little as $3.50 per thousand tablets in some instances. The varying prices of Clark & Clark's tablets were also evidenced by postal cards periodically sent to the trade in many thousands offering the products of Clark & Clark for sale. The postal cards contained various headings as follows: "Special Offer," "Final Sale, 10 Days Only," "5 Days Only Amphetamine Sulfate," "By Popular Demand, 10 Days Only, Amphetamine Sulfate," "10-Day Special." A picture of several tablets usually featured the lower portion of each postal card.

Morris insisted that the reason which caused the change of the form and appearance of the Clark & Clark tablet was because he wanted a deeper groove in the tablet to facilitate its breakage into halves and quarters as the patient required lesser dosage than the whole tablet.

Clark & Clark also produced 5-milligram amphetamine sulfate tablets. This tablet was likewise changed for the claimed purpose of deepening its single groove.

The amount of material used in a tablet which contains the drug is usually a very small fraction of the size of the entire tablet, the remainder being a binder. Morris agreed in his testimony that he could make amphetamine sulfate tablets in an infinite number of sizes, shapes and distinctive designs, and these would contain the same dosage and facilitate the breakage equally ***997** with the tablet Clark & Clark presently produced, thereby preserving the same advantages of his present tablet.

A large volume of testimony was introduced to show that where prescriptions calling for benzedrine, benzedrine sulfate, benzedrine sulfate S.K.F. and amphetamine sulfate S.K.F. were tendered to druggists they were filled in part, or in whole, with the tablets of Clark & Clark. Some 25 such prescriptions were described as having been filled by different druggists in New York and 8 in Philadelphia. It is to be noted that the prescriptions usually called for 12 tablets. The cost to the consumer was generally about 75 cents, although in one or two cases the price to fill a prescription was as low as 50 cents and as high as 95 cents. The 33 prescriptions were filled at an aggregate cost to the purchasers of $23.85. This cost to the consumer would not appear to reflect any saving to him by reason of the substitution for the prescribed drug.

In most of the substitutions the prescription was filled by the druggist with all of the tablets of Clark & Clark. In a small number of cases the mixture of

tablets put up by the druggists consisted in part of plaintiff's and in part of Clark & Clark's.

The practice of substituting drugs is regarded by the profession of druggists as highly reprehensible, but apparently the druggists who perpetrated the substitutions, demonstrated in the evidence before us, felt that the tablets were so identical in appearance that they could substitute them with security, even to the extent of mixing the tablets of the plaintiff and Clark & Clark in one package.

It is also to be noted that any savings effected by the druggist in the purchase of Clark & Clark tablets at a price considerably lower than the price of plaintiff's tablets were not passed on to the ultimate consumer, but benefited either the distributor or the druggist, or both. One of defendants' expert witnesses, a physician specializing in obesity, calculated that approximately 30% of his fee was allocated to the cost of amphetamine sulfate tablets which he personally dispensed to each of his patients. Before purchasing his supply of tablets from Clark & Clark, he obtained them from the plaintiff at a cost of approximately $22 per 1000. Later he changed his purchases to Clark & Clark at a cost of only $3.50 per 1000. However, he conceded that his fees were not decreased after he had changed his supplier, again demonstrating that any savings on the cost of the tablets were absorbed before they reached the ultimate consumer.

Through their witness, A. C. Herting, the defendants introduced into evidence a booklet entitled "Pennsylvania Formulary (P. F.)," consisting of 59 pages, in which were listed 190 prescriptions or remedies. It was published in 1943 and on its inside cover it contained the statement of policy over the signature of the secretary of the "Joint Comm. of the Penna. Pharm. Assn. and the Medical Society of the State of Penna." It also contained an introduction signed "The Joint Committee." Herting was named as Vice-Chairman of, and Chemist and Pharmacologist for, the Joint Committee.

Suggestions and recommendations were made to physicians with regard to prescription and dispensing practices, and alphabetical and therapeutical indices preceded the listings of the prescriptions.

The following formulas appeared in the order of their numbers:

"2 Argentum Iodum Colloidalis

*** * * * * ***

"Also it may serve as excellent suspension for ephedrine salts and *Pen-Phetamine* (1 gr. per oz.) in nasal work." (Italics ours)

"4 Capsulae Amphetaminae Capsulae *Pen-Phetamine* 5 mgm (3/40 gr)

Amphetamine Sulf. (*See # 130*) 1½ grs
Sacch. Lac 60 grs
Fiat Caps No. XX
Color Yellow" (Italics ours)

"5 Capsulae Amphetaminae Capsulae *Pen-Phetamine* 10 mgm (3/20 gr)

Amphetamine Sulf. (*See # 130*) 3 grs
Sacch. Lac. 100

grs
Fiat Caps No. XX
Color Red" (Italics ours)

"28 Capsulae Thyroid. Comp. (1-2-3)

No. 1

Thyroid	1 gr
Prophetamine Sulf.	1/12 gr
Atropine Sulf.	1/360 gr
Aloin	¼ gr
Carbo Activat	1/20 gr
Sacch Lac	3½ grs

Fiat Caps. No. 1 (grey color)
Sig one before breakfast

***998 No. 2**

Thyroid	1 gr
Phrophetamine Sulf.	1/12 gr
Atropine Sulf.	1/360 gr
Sacch Lac	1½ grs

Fiat caps. No. 1 (white color)
Sig one before lunch

No. 3

Thyroid 1 gr
Prophetamine Sulf. 1/12 gr
Atropine Sulf. 1/360 gr
Sacch Lac 3½ grs
Phenobarbitalis ¼ gr
Solution Amaranth-qs to pink color
Fiat Caps. No. 1 (pink color)
Sig one at 4 P. M.

A controlled and accelerated thyroid therapy of especial value in treating most obesity cases. *See monograph #130.*" (Italics ours)

"124 Nebula Sulfo-*Pen-Phetamine*

Penphetamine Sulfate 3/5 gr
Sod. Sulfathiazole 11¼ grs
Sod. Sulfite 9 grs
Aqua Dest-qs 1 oz
Liq. Carmini qs to deep rose color." (Italics ours)

"130 Pen-Phetamine

The P. F. synonym and brand name of Amphetamine Base and Sulfate

"Benzyl-methyl-carbinamine has an alkaloidal character chemically similar to Epinephrine and Epedrine corresponding to a Racemic Desoxy-nor-ephedrine (See Merck's Index).

"A colorless liquid soluble in alcohol, ether and some essential and fixed oils.

"Pen-Phetamine Sulfate

is a white odorless powder soluble in about 10 parts of water, slightly soluble in alcohol and insoluble in ether. The aqueous solution is practically neutral. The sulfate corresponds to about 73% base.

"While it is similar to Ephedrine as a vaso-constrictor yet therapeutically it differs considerably from Ephedrine."

"It is a circulatory stimulant and stimulates the central nervous system. It is of value in sinusitis, vasomotor rhinitis, hay fever, asthma, urticaria, pertussis, serum sickness, stimulant in nervous exhaustion, depressive psychosis, narcolepsy, post encephalitic parkinsonism, various depressive and asthenic states, hypotension and relaxation of spasm. It has been found exceptionally valuable in the melancholia of the climacteric and as a homostimulant in the addenda treatment of loss of libido, impotence, premature senility and sexual neurasthenia.

"It appears effective for various forms of nausea, `curbs' appetite and apparently aids in consuming, i. e. `burning up' of carbo hydrates for which reason it has given good results as an addenda in the treatment of various forms of obesity and the syndrom of diabetes.

"It is contraindicated in cardiovascular disease, hypertension and extreme nervousness.

"Dose 2.5 to 10 mgm (1/24 to 1/6 gr)

"Pen Phetamine is manufactured by the Clark & Clark Co., Philadelphia, New York and Camden by authority of the Joint Committee.

"The Research work is supervised by and control in manufacture done by Samuel P. Sadtler & Sons, Inc., Chemists, Philadelphia."

It is to be noted that in formulas numbers 4, 5, and 28 references were made to formula 130, in which special mention is made of the source of amphetamine sulfate as manufactured by Clark & Clark by authority of the Joint Committee. No such authority was granted or existed. No other reference of source of this nature appears in the entire booklet except for one or two isolated instances. Incidentally, the location of Clark & Clark was solely in Camden, New Jersey, for manufacturing purposes and not in New York and Philadelphia as stated.

The evidence also disclosed that Samuel P. Sadtler & Sons, Inc., did not supervise the research work or control the manufacture of the product, as claimed in the Formulary, but that Philip Sadtler, a son of a member of the firm and a witness for defendants, insisted that the firm was in no way connected with Clark & Clark.

When Herting was interrogated as to the authority for the issuance of the booklet, he testified as follows:

"I was only the work horse of the committee and that book was published, just as it appears on the front of the book, by the Joint Committee of the State Medical Society of the State of Pennsylvania of which Professor Reimann is a member, and the Joint Committee contains men who are

members of the medical examining ***999** board. They passed on what I wrote. I did write the thing, that is right. I done the editing, I arranged it alphabetically, I got most of the titles together; I checked dosage, but they passed on all that. You don't think for one moment that the Medical Society of the State of Pennsylvania would let me go ahead and carry something to a printer and shoot it out and hobble it on them." (Record pp. 1047, 1048)

The Pennsylvania Formulary was distributed to physicians in the State of Pennsylvania and to all registered pharmacists through the Pharmaceutical Association of Pennsylvania.

Herting further testified that by reason of his personal and family experiences with amphetamine sulfate he sought out Clark & Clark and gave it the listing as described in the Pennsylvania Formulary.

Morris testified that Herting contacted him and sought his permission to list the amphetamine sulfate of Clark & Clark under the name of Pen-Phetamine in the Formulary and that he, Morris, had little interest in such publication. Morris testified that it was Herting who advised the filing of the name Pen-Phetamine in the Patent Office to obtain the trade-mark.

Morris, notwithstanding his lack of interest in the Pennsylvania Formulary, noted on the advertisements of sales of Clark & Clark amphetamine sulfate tablets, which were periodically distributed by the thousands to the trade, that the product Pen-Phetamine was listed in the Pennsylvania Formulary. Pen-Phetamine was also advertised as being a registered trade-mark, although registration had been refused.

Herting testified that at one time he was part owner of the Standard Medical Laboratories of 417 Mickle Street, Camden, New Jersey, which turned out the eucathesian tablets with cross scored grooves on their faces. This was the same company from which Clark & Clark purchased its machinery,

equipment and punches to produce the 10-milligram amphetamine sulfate tablets, and in fact, continued to do business at the same address.

Herting insisted that he did not know Morris or the firm of Clark & Clark until he happened upon it in search for the manufacturers of the amphetamine sulfate of which he was in quest.

On cross-examination Herting was asked and replied:

"Q. Now, this Formulary was prepared and the text written by you, was it not? A. That is right." (Record p. 1047)

"Q. Why did you refer in the Formulary to the Clark & Clark thyroid preparation, why did you refer to it as profetamine sulphate, that is, by the trademark of Clark & Clark rather than by the name `Amphetamine Sulphate' which had been approved by the American Medical Association as the non-proprietary name for it? A. I don't even know did I have profetamine in that? Is that No. 78, Clarkotabs?" (Record p. 1055)

"Q. That is, you just saw some trademark which you looked at which was profetamine and it was Clark & Clark's? A. Exactly. Pen-Fetamine was not Clark & Clark at that time. It has since applied for it as nearly as I know, to protect themselves I understand. The medical men didn't get this copyrighted which I told them was wrong and the medical men didn't want any trademarks on their synonyms which in that I agreed to this extent, that the strictly professional man who gives his life work to humanity, he does not value a trademark like you would or like the merchant. I have several patents, and my father before me. I think my father did get a dollar a week really one time; he done something that meant 40,000 a year for somebody." (Record, pp. 1056, 1057)

The publication of this Formulary gave rise to considerable objections from various members of the medical profession in the State of Pennsylvania.

This is evidenced by the following letters addressed to a member of the Joint Committee:

"I am writing to you as a Member of the Joint Committee, which has published the 1943 Edition of the Pennsylvania Formulary, because I do not happen to have Dr. Palmer's address. I was greatly surprised to find on Page 9, Formula #29, a capsule called `Capsulae Uva Ursi Comp.' It is footnoted as being `Helpful in some types of Diabetes.' I realize that you had nothing to do with this volume, but wish you would pass this letter on to the proper persons.

"The Government and the American Diabetes Association have spent considerable time, effort, and money in obtaining convictions against the manufacturers of preparations which can be taken by mouth, advocated in the treatment of diabetes. It is a little discouraging therefore, to see ***1000** that the Pennsylvania State Medical Society officially endorses and recommends, by implication at least, that these capsules may be used for the treatment of diabetes. The State Commission on Diabetes has been preaching since its inception, that there is no preparation which can be given by mouth as an insulin substitute. I consider that this is unethical advice to members of the State Society. I can see little difference in this from the quackery practiced by the drug houses, against whom convictions have been obtained in Federal Court. I am sure it will do much to offset the educational program which the Diabetic Commission has been attempting to institute for the past three or four years, and it is very discouraging indeed, that any State-appointed and approved Committee would be so negligent as to let a matter of this sort appear in their official publications.

"The danger to the patient himself cannot be minimized. I am sure that many general practitioners will use these capsules instead of insulin, and allow the diabetes to drift into complications which would prove quite serious. I would like to protest emphatically against this, not only as President of the

American Diabetes Association, but as a member of the Pennsylvania State Society. I feel that some steps should be taken to correct this very serious and dangerous advice given to the members." (Letter of Joseph T. Beardwood, Jr., M. D., September 14, 1943.)

"I am in receipt of the Pennsylvania Formulary prepared by the Joint Committee of the Pennsylvania Pharmaceutical Association and The Medical Society of the State of Pennsylvania and note that on page ii criticism and suggestions are invited.

"As far as criticism may be offered, it is hard for me to see how or why the medical authors, representatives of the Pennsylvania State Medical Society, could participate in a publication of this sort. It is of no credit to the Society. It is full of prescriptions containing useless antique galenicals and full of `shotgun' prescriptions composed in mixtures of Latin and English. As stated in the introduction of the pamphlet, many of the prescriptions are indeed `gems.' No. 79 for example contains 13 ingredients.

"The `Therapeutic Index' is particularly offensive. It is incomplete, misleading, and dangerous. Examine, for example, prescriptions No. 9 and 130 recommended for premature senility, or No. 112 for fever, or No. 29 for diabetes. What could Elixir Hemostatici possibly accomplish, and what is the indication for the use of metallic tin (No. 25)? Prescription 64 containing ammonium chloride and `Spec. Med. Chionanthus' (sic!) is said to be `highly serviceable in all cases of hepatic pathology * * *.' The recommendation of `Penphetamine,' `Pen-Argyl,' and `Penpix' is highly objectionable.

"I am sure that the publication of this pamphlet will be regretted and will cause consternation, particularly to teachers of pharmacology, therapeutics, and medicine in the medical schools of Pennsylvania and elsewhere. Unless the authors see fit to rewrite the Formulary in toto in the light of modern

therapeutics, my only suggestions would be to recall as many copies as possible and never to publish a revision." (Record, pp. 1044-1046, Hobart A. Reimann, M.D., Professor of Medicine, Jefferson Hospital, Philadelphia, Pa.)

The last letter was also published in the Pennsylvania Medical Journal for October 1943, Vol. 47, No. 1.

In the official journal of the Pennsylvania Pharmaceutical Association "The Pennsylvania Pharmacist," October 1943, Vol. XXV, No. 3, the following appears on the coverpage:

"Due to Inaccuracy Delete Formulas Number 4, 5, 28, 124 and 130 in the Pennsylvania Formulary."

In the March 1943 "Pennsylvania Medical Journal," page 618, the following letter was printed:

"November 23, 1943 "Re: The Recently Issued Pennsylvania Formulary

"To the Members of

"The Medical Society of the State of Pennsylvania

"Dear Doctor:

"The following quotation is an excerpt from the minutes of the February 11, 1943, meeting of the Board of Trustees:

"`Chairman Palmer reported that the Pennsylvania Pharmaceutical Association proposes to supply for distribution to the membership of our State Society a small printed pamphlet containing certain approved therapeutic formulas and prescriptions fashioned from the United States Pharmacopeia. It is estimated that it may cost the Society about $300 to

distribute ***1001** them by mail. The State Public Assistance Department has also agreed to distribute some. Under an adopted motion, which was made by Dr. Scattergood and seconded by Dr. Gagion, the President of the Society will appoint a committee of three, with Dr. Palmer as chairman, to act in conjunction with the State Pharmaceutical Association on this proposal.'

"This pamphlet was distributed in August, 1943, to the physicians and pharmacists of Pennsylvania under the title `Pennsylvania Formulary' (P.F.).

"The officers of The Medical Society of the State of Pennsylvania have received written criticism from several sources which they believe to be justified for the following reasons:

"1. Many of the prescriptions do not follow late and accepted principles of scientific therapeutics.

"2. The discussion of treatment given in the fine print beneath prescriptions in some instances suggests unscientific standards of medical practice.

"3. Several new names were introduced for ordinary drugs with the prefix `Pen' to indicate their use in the P.F.

"The name Pen-Phetamine was coined for `amphetamine base and sulfate,' and the further statement was made that `Pen-Phetamine is manufactured by Clark & Clark, Philadelphia, New York, and Camden, by authority of the Joint Committee.' (Quotes are from the P.F.) No such authority was given by the Joint Committee, and furthermore the Committee had no right to grant any such authority for any such drug or formula to any manufacturer. This drug has been manufactured for years by Smith, Kline & French under the name of `Benzedrine.'

"After the attention of the Board of Trustees of The Medical Society of the State of Pennsylvania had been drawn to the aforementioned facts, the

Board took action described in the minutes of its meeting of October 4, 1943, as follows:

"`After a full discussion of the question it was moved by Dr. Yeager, seconded by Dr. Klump, that the recipients of copies of the Pennsylvania Formulary be requested, by a letter setting forth the oversights on the part of the Joint Committee, to discard the Pennsylvania Formulary.' This motion was later amended to provide for the appointment of a committee by President Anderson `to study the situation and compose and approve the proposed letter, and report to the Board of Trustees."

"This letter is the result of deliberations of the committee authorized by the Board of Trustees of The Medical Society of the State of Pennsylvania, and its purpose is to notify the membership that the Society withdraws its sanction of the Pennsylvania Formulary and hereby respectfully requests each member to discard it."

We can conclude only that the Pennsylvania Formulary was a device whereby the product of Clark & Clark was expected to receive exceptional advertising to the doctors and druggists of the State of Pennsylvania. It is quite apparent that it was schemed for such purpose, and not very intelligently, because its ultimate failure should have been easily anticipated.

The booklet was apparently the work of Herting only, and was not the product of the responsible authorities of the Pharmaceutical Association or Medical Association of Pennsylvania. His association with the very firm from which Clark & Clark bought their equipment, at the very address in which it continued its business, appears to be more than the coincidence which Herting claimed for it. Ironically, too, witnesses for plaintiff testified that during the pendency of the trial a prescription was presented to Herting calling for plaintiff's product and the product of Clark & Clark was substituted when the prescription was filled.

The whole episode of the Pennsylvania Formulary is an indication of the unfairness with which Morris exploited the sale of the Clark & Clark product.

Letters were offered in evidence which were signed by Morris for Clark & Clark. When examined in connection with the other evidence they throw a strong light on the unfair business practices in which Clark & Clark indulged.

On June 19, 1942, Clark & Clark wrote one M. Brown, in Mississippi, offering him the exclusive distribution of its product for the entire state.

The letter, dated June 19, 1942, follows:

"Recently the Northern States Corporation have referred to us your inquiry on Amphetamine Sulphate. The reason for this is because we are the sole distributor of this product.

***1002** "If you are interested in this item our net price to you will be $300.00 per Kilo, and $5.00 per 1,000 for 100,000, 10 milligram tablets to be shipped in one delivery.

"We are in a position to offer you the exclusive distributorship on our product for the entire State of Mississippi; provided, of course, that you will not cut below our schedule prices. The schedule prices to be to retail drug stores, hospitals, and dispensing physicians; bottles of 100 tablets, 10 milligram, $1.60; bottles of 250, 10 milligram, $3.40; bottles of 1,000, 10 milligram, $12.00.

"We will also give you $100.00 worth of tablets, if you will immediately spend up to this amount for the promotion and advertising of this product to your accounts.

"Amphetamine Sulphate, as you no doubt know, must comply with the specifications of the N. N. R., also we guarantee we are not infringing on any other pharmaceutical house's manufacturing processes of this chemical compound, and samples of our Amphetamine Sulphate have been submitted to the Federal Food and Drug Administration and have been approved by same.

"Enclosed are samples of our 10 milligram tablets, and if you are interested in being one of our distributors please write and let us know by return mail."

Morris admitted that his letter to Brown characterizing Clark & Clark as the sole distributor of amphetamine sulfate was misleading. He further admitted that he never later informed Mr. Brown that Clark & Clark was not the sole distributor of amphetamine sulfate. His only explanation for this misrepresentation was that it was a mistake.

Another misrepresentation in the letter worthy of note is the statement in which Mr. Brown was advised that samples of Clark & Clark's product had been submitted to the Federal Food and Drug Administration and had been approved by it. The evidence showed there had never been a submission to this federal agency of Clark & Clark's product. It appeared that tablets had been purchased from The Lannett Company by two government inspectors and nothing further was heard from the agency. Morris contended that it was his conception that failure of the government agency to communicate with him in two weeks authorized him to represent that it had approved his product.

In another letter to an addressee unknown to us, dated June 4, 1943, Morris wrote:

"Until several months ago Commercial Solvents offered for sale Amphetamine, N. N.R. under the name Phenyl-iso-propylamine. In view of the fact that it was necessary for them to convert their equipment over to the

manufacture of other important chemicals for the armed forces, our supply of amphetamine from this source naturally was cut off.

"After our supply was stopped we retained an outstanding group of research chemists, Samuel P. Sadtler & Son, Inc. of Philadelphia, to work on the synthesis of amphetamine, and after several months of research the synthesis of this drug was accomplished.

"Due to the fact that our research chemists have been able to synthesize amphetamine, as stated above, we are now in a position to offer you amphetamine sulfate powder for manufacturing purposes. Our price is $350.00 per kilo, and $325.00 per kilo in quantities of five kilos or more. If you are interested in the purchasing of any of this material we would be pleased to be of service to you."

There is no evidence to support some of the representations contained in this letter and the proofs show that there is no basis for their truth. Whatever the reason for the discontinuance of the sale of amphetamine sulfate by Commercial Solvents, it was not that given by Morris. The "Sadtler" whom Morris retained to synthesize the drug was the son of a member of the firm of Samuel P. Sadtler & Son, Inc., who, when he appeared as a witness for the defendant, insisted that his work for Morris was not connected with the firm of Samuel P. Sadtler & Sons, Inc. but separate and distinctly apart from the activities of that firm.

The defendants charge the plaintiff with unfair competition in the use of the name "Benzedrine Sulfate." They submit that this name was used as the generic name of the drug since its introduction; that most doctors know the drug only by that name; that plaintiff invariably refers to the drug as Benzedrine Sulfate in its literature to the trade, and that where the name of a product becomes generic the right to use it passes to the public and it is no longer entitled to protection. The defendants conclude from this argument

that ***1003** the filling of prescriptions for Benzedrine Sulfate by druggists are not substitutions.

The facts in the case do not support the position that Benzedrine Sulfate is the generic name of the drug. The drug was known to doctors and druggists by its chemical name, benzyl methyl carbinamine prior to 1938 at which time the generic name, amphetamine sulfate, was adopted by the American Medical Association. Benzedrine Sulfate is plaintiff's registered trademark for amphetamine sulphate. This fact was shown to be known by the trade. As Morris himself testified an ethical pharmacist when presented with a prescription for Benzedrine Sulfate would fill it with plaintiff's tablets and when presented with a prescription for Profetamine would fill it with Clark & Clark's tablets. If the prescription called for amphetamine sulfate, the druggist could then choose his brand in filling the prescription. The evidence fails to show the plaintiff's product was sold other than with labels containing the words "Benzedrine Sulfate (amphetamine sulfate)", or "Benzedrine Sulfate (racemic amphetamine sulfate)" or "Benzedrine Sulfate, Brand of racemic amphetamine sulfate," although we fail to see how its sale under the trade-mark name of Benzedrine Sulfate alone would constitute unfair competition with the defendants where the latter sells its product under the name of Profetamine which it claims is a brand of amphetamine sulfate.

Aside from these considerations, the legal principles which the defendants would have us apply to the sale of amphetamine sulfate by the plaintiff as Benzedrine Sulfate solely, if that were the case, are not material to this action for infringement of the patent and unfair competition. The cases cited by the defendants, Singer Mfg. Co. v. June Mfg. Co., 163 U.S. 169, 16 S. Ct. 1002, 41 L. Ed. 118, and Singer Mfg. Co. v. Bent, 163 U.S. 205, 16 S. Ct. 1016, 41 L. Ed. 131; Merriam Co. v. Syndicate Publishing Co., 237 U.S. 618, 35 S. Ct. 708, 59 L. Ed. 1148; Kellogg Co. v. National Biscuit Co., 305 U.S. 111, 59 S. Ct. 109, 83 L. Ed. 73; Bayer Co. v. United Drug Co., D.C.,

272 F. 505, are concerned with the legal principle that when a name, whether arbitrary or coined by the inventor, becomes the identifying and generic name of the object of the patent, this name becomes part of the public domain, *when the monopoly which the patent creates ceases* and that it may be used by others thereafter engaged in selling the same product provided it is not used to deprive others of their right or to deceive the public. The use of the name must then be accompanied with such indications that the public will be unmistakably informed of the true manufacturer.

The patent rights to manufacture and sell this product have not expired. The trade-mark rights to the name Benzedrine Sulfate have not expired. There is no evidence to show that Benzedrine Sulfate has become the generic name of the drug. The name of the drug is known only to doctors and druggists, who are well informed and completely familiar with it, by its chemical and generic names, as well as the name by which it is offered for sale by the plaintiff. The charges of the defendants that the use of the name, Benzedrine Sulfate, by the plaintiff, constitutes unfair competition, fails for these reasons.

The common law cause of action for unfair competition exists separate and apart from actions for infringement under the statutory law of patents and trademarks. The basis of the action is found in the words "unfair competition." What is unfair competition is a question of fact, the determination of which is made upon the facts of the particular case. That which is unfair trade in one case may not be unfair in another where the circumstances surrounding the alleged unfair acts are different. "The general purpose of the law of unfair competition is to prevent one person from passing off his goods or his business as the goods or business of another." Standard Oil Co. of New Mexico v. Standard Oil Co. of California, 10 Cir., 56 F.2d 973, 977. The object of the law is obvious. It seeks to protect the honest business man in that fair trade to which he is entitled; to punish the unfair trader who attempts to take away such business by dishonest or unfair

means; to protect the public from deception and unfair business practices. Atlas Mfg. Co. v. Street & Smith, 8 Cir., 204 F. 398, 405, 47 L.R.A.,N.S., 1002; J. N. Collins Co. v. F. M. Paist Co., D.C., 14 F.2d 614, 615. The diversion of an established business built up over a period of years through good will, advertising and other legal means through such unfair business practices upon the part of another constitutes an invasion of the right protected by the action of unfair competition which provides a method of relief. Industrial Rayon Corporation v. Dutchess Underwear Corporation, 2 Cir., 92 F.2d 33, 35, certiorari ***1004** denied 303 U.S. 640, 58 S. Ct. 610, 82 L. Ed. 1100.

Unfair competition is based on equitable principles. It must be distinguished from actions of infringement which involve the violation of exclusive rights to manufacture, use or sell a product, or to use a word, mark or symbol. Unfair competition involves any violation of a right arising from the operation of an established business. Although one may have an equal right to use the word, mark or symbol of another on products produced by him, he will not be permitted to use such word, mark or symbol in such a manner as to deceive or be capable of deceiving the public as to the origin, manufacture or ownership of the product. Dennison Mfg. Co. v. Thomas Mfg. Co., 3 Cir., 94 F. 651; G. W. Cole Co. v. American Cement & Oil Co., 7 Cir., 130 F. 703. A discussion of these principles as related to the confusion of goods as an unfair method of competition appeared in the Cole case, in which the court stated:

"Whether such confusion has been or is likely to be produced by the acts charged, is a question of fact to be resolved either by evidence of actual sales of the one product for the other, of actual mistake of one for the other, of fraudulent palming off of one for the other, or, on the other hand, failing such evidence, by comparison of the two brands to determine whether the one can be readily mistaken for the other, even by the inattentive and unobserving retail purchaser." 130 F. at page 705.

The practice described in the case of Winthrop Chemical Co. v. Weinberg, 3 Cir., 60 F.2d 461, is analogous to that in the case before us. In the Winthrop case an established pharmaceutical company, which dealt exclusively with physicians and pharmacists and spent large sums for advertising, and whose products had won the confidence of physicians by their excellence and dependability, so that physicians specifically prescribed them, sued for an injunction restraining a druggist from surreptitiously substituting for plaintiff's product "Luminal," a brand of phenobarbital, a different phenobarbital. In granting relief to the plaintiff the court held:

"As the proof is that Luminal commands a higher price than unbranded phenobarbital costs a druggist, the purpose of the defendant in surreptitiously substituting a different phenobarbital than the one ordered by the doctor is clear. No contention is made that any mistake was made or that the druggist did not have Luminal on hand. In fact, he justifies his conduct and asks this court to approve of his deceptive substitution. This we decline to do. The question before us is simply a case of dishonest deception, and, as said in Vick Chemical Co. v. Vick Medicine Co., D.C., 8 F.2d 49, 50, the `underlying principle of law of unfair competition is to prevent substitution by deception,' a principle recognized by this court in Rosenberg Bros. & Co. v. Elliott, 3 Cir., 7 F.2d 962. In ordinary commercial affairs, `substitution by deception' is wrongful, but, when in the healing art there is `substitution by deception,' greed may reach the grade of malice." 60 F.2d at page 463.

The rulings in this field of litigation circumscribe the acts complained of by the plaintiff herein.

In the case of W. & H. Walker v. Walker Bros. Co., 1 Cir., 271 F. 395, certiorari denied 256 U.S. 702, 41 S. Ct. 623, 65 L. Ed. 1179, the following appears:

"Unfair competition in commerce results from actual misdoings, or from an assembly of circumstances, which are calculated, in and of themselves, to mislead the public, or, as it is sometimes expressed, `the average trade.'"

"It is quite true, in cases of unfair competition, in the usual phase, that the question depends upon the purpose, or upon the question of good or bad faith, while upon another phase the question would be whether a situation, in and of itself, without regard to the question of good or bad faith, the ways and means are, in and of themselves, calculated to deceive members of the public into buying one thing when they think they are getting another. The questions always are whether trade is being unfairly interfered with, and whether the public is being cheated into buying and paying for something which it is not, in fact, getting." 271 F. at pages 397, 398.

And in F. W. Fitch Co. v. Camille, Inc., 8 Cir., 106 F.2d 635, at page 640, it is stated:

"The evidence in this case, however, showed, and the court found the fact to be, that purchasers had been actually deceived. Actual deception having been shown establishes the probability or likelihood of deception. But it is urged that no wrongful act of defendant caused a single instance of substitution or confusion. A similar argument was presented in Wolf Bros. & Co. v. ***1005** Hamilton-Brown Shoe Co., 8 Cir., 206 F. 611, 617. In disposing of this contention this court said: `If a manufacturer or wholesale dealer willfully puts up goods in such a way that the ultimate purchaser will be deceived into buying the goods of another, it is no defense that he does not deceive and has no intention of deceiving the retailer, to whom he himself sells the goods. The question is whether the defendants have or have not knowingly put into the hands of the retail dealers the means of deceiving the ultimate purchaser.'"

It is clear that one will not be permitted to palm off his goods as those of another, no matter how subtle are the means. Enterprise Mfg. Co. v. Landers, Frary & Clark, 2 Cir., 131 F. 240.

The last mentioned case was cited in the case of Sinko v. Snow-Craggs Corporation, 7 Cir., 105 F.2d 450, where the following language was used:

"The law of unfair competition stresses business integrity, encourages legitimate trading, and protects good will against spoliation. However, it is not true that all acts done in the trade, which the average person would describe as unfair, are actionable. `As a manufacturer, one has a perfect right to make any article of commerce not covered by a patent monopoly * * *. As a distributor, however, he must respect those methods of honest and upright dealing which forbid one competitor from adapting practices which are now well understood to be unfair or fraudulent.' William H. Keller, Inc., v. Chicago Pneumatic Tool Co., 7 Cir., 298 F. 52, 57, certiorari denied 265 U.S. 593, 44 S. Ct. 637, 68 L. Ed. 1196. The existence of a right of action depends upon the peculiar facts of each case, turning on whether what is done by one person to get the business of another is done unfairly, i.e., by means that involve fraud or deceit.

"In other words, equity will protect the honest, and restrain the dishonest, trader. The general rule in these cases has been admirably stated in Enterprise Mfg. Co. v. Landers, 2 Cir., 131 F. 240, 241, in this way:

"`* * * a court of equity will not allow a man to palm off his goods as those of another, whether his misrepresentations are made by word of mouth, or, more subtly, by simulating the collocation of details of appearance by which the consuming public has come to recognize the product of his competitor.'

"That is to say, the doctrine underlying unfair competition cases is to restrain deceitful and fraudulent competition in whatever garb of misrepresented identity it assumes." 105 F.2d at page 452.

Where a defendant sold a compound similar in taste and appearance to plaintiff's compound, both sold for the same uses, but defendant's product was sold at a lower price, evidence that defendant's effort to produce a market was not directed so much to showing the merits of its preparation as to demonstrating its practical identity with plaintiff's compound, and since it was sold at a lower price to the purchasing druggist he could, in his own interest, substitute defendant's compound for plaintiff's compound, defendant was found guilty of unfair competition. Warner & Co. v. Lilly & Co., 265 U.S. 526, 44 S. Ct. 615, 68 L. Ed. 1161. The following language appears in the opinion of the Supreme Court:

"There is much conflict in the testimony; but on the whole it fairly appears that petitioner's agents induced the substitution, either in direct terms or by suggestion or insinuation. Sales to druggists are in original bottles bearing clearly distinguishing labels and there is no suggestion of deception in those transactions; but sales to the ultimate purchasers are of the product in its naked form out of the bottle, and the testimony discloses many instances of passing off by retail druggists of petitioner's preparation when respondent's preparation was called for. That no deception was practiced on the retail dealers, and that they knew exactly what they were getting, is of no consequence. The wrong was in designedly enabling the dealers to palm off the preparation as that of the respondent. Coca-Cola Co. v. Gay-Ola Co., 6 Cir., 200 F. 720; N. K. Fairbank Co. v. R. W. Bell Mfg. Co., 2 Cir., 77 F. 869, 875, 877, 878; Lever v. Goodwin, L. R. 36 Ch.Div. 1, 3; Enoch Morgan's Sons Co. v. Whittier-Coburn Co., 9 Cir., 118 F. 657, 661. One who induces another to commit a fraud and furnishes the means of consummating it is equally guilty and liable for the injury. Hostetter Co. v. Brueggeman-Reinert Distillery Co., 8 Cir., 46 F. 188, 189." 265 U.S. at pages 530, 531, 44 S.Ct. at page 617, 68 L. Ed. 1161.

The case of Coca-Cola Co. v. Gay-Ola Co., 6 Cir., 200 F. 720, certiorari denied 229 U.S. 613, 33 S. Ct. 773, 57 L. Ed. 1352, cited in the Supreme

Court opinion above, presented ***1006** a similar set of facts. The court used the following language:

"Accordingly, we find it recognized by this court that, in a suit for unfair competition, it is not necessary to show that the immediate purchasers were deceived as to the origin of the goods; but even if they thoroughly understand that they are buying the counterfeit, and not the genuine, the manufacturer of the counterfeit will be enjoined from selling it to dealers with the purpose and expectation that it shall be used by the dealers to deceive the consumer." 200 F. at pages 722, 723.

The case of Champion Spark Plug Co. v. Emener, D.C., 16 F. Supp. 816, is in point. The court citing Warner & Co. v. Lilly, supra, stated:

"The facts and circumstances already mentioned necessarily make it both easy and natural that spark plugs manufactured by the plaintiff, but partially worn out by use and reconditioned by the defendant as aforesaid, should be sold by unscrupulous customers of the defendant in such a manner as to deceive, sometimes expressly and sometimes by implication, purchasers desiring new Champion plugs into the belief that such reconditioned plugs are new ones, and it is not surprising that this is the result of the practices of the defendant here complained of. It is, of course, elementary and fundamental that a person is legally chargeable with having intended to cause whatever is the natural and ordinary result of acts knowingly committed by him. So, it is a rule, too well settled to require the citation of authority, that even where, as here, a defendant does not actually intend to deceive any one, his acts may constitute unfair competition within the meaning of the law, if that is the ordinary and probable result of such acts; and as the sale, by customers of defendant, to the public, of reconditioned plugs when Champion plugs are called for is a fraud on the public and unfair competition with plaintiff, the result of which is to deprive it of the sale of new Champion plugs and to injure its reputation and good will, and as the

defendant sells these plugs to his customers for resale to the public, and thereby furnishes to them the means of, and temptation for, their deceiving the public and thereby injuring the plaintiff as already shown, he cannot escape responsibility for the resulting deception and injury on the plea that he did not himself deceive any one nor instruct or authorize his customers to do so." 16 F.Supp. at page 822.

Counsel for both plaintiff and defendants cited the case of Upjohn Co. v. William S. Merrell Chemical Co., 6 Cir., 269 F. 209, certiorari denied 257 U.S. 638, 42 S. Ct. 50, 66 L. Ed. 410. In that case the plaintiff, a well known manufacturer of pharmaceutical preparations, became convinced that there was a good field for the marketing of phenolphthalein, a laxative or cathartic drug, and selected a distinctive tablet in which to put this drug on the market. The distinctive qualities of the tablet were color, shape, flavor and size. The plaintiff adopted the arbitrary tradename of "Phenolax" or "Phenolax Wafer." Before the tablet was put on the market the trade-names and the tablet were extensively advertised and a force of salesmen promoted the introduction.

Within a few months, the defendant, a manufacturing chemist, determined a short time thereafter to make the same drug in the same form and put out a tablet which was indistinguishable from plaintiff's tablet as to shape, size, color and flavor. Defendant, however, did not use the name "Phenolax" and put up his product in a different package from that of the plaintiff.

In a suit for unfair competition it was held that although the facts were close the plaintiff was not entitled to relief for the reason that there had not been a public acquisition in the plaintiff's preparation of certain distinctive qualities for his tablet. The court said:

"The opinions of this court, within recent years, have discussed many aspects, if not all, that arise in unfair competition. It would be useless to

repeat what has been there said, or to refer again to the decisions of the Supreme Court and other courts there cited. They affirm or lead to the conclusions that plaintiff can have relief only against an attempt to palm off on the purchasing public the goods of defendant as the goods of plaintiff; that where the imitation relates only to matters as to which the defendant has, prima facie, a right equal to plaintiff, there must have been a public acquiescence in plaintiff's appropriation of these things for his product a public sanction of the taking sufficient to have created that secondary meaning whereby they have become, to the public, indicia of origin; and that while, when ***1007** the plaintiff has selected as his means of identification words or marks that are arbitrary, and hence proper trade-marks, his title is at least initiated by the appropriation, yet as to those means of identification, which are descriptive, or which, for any reason, are known and open to all, there is no basis, in principle or in authority, for the creating of a title or quasi exclusive right in plaintiff, except the theory that there has been this public sanction of plaintiff's appropriation, by acquiescence which has continued long enough and under circumstances suitable to raise a presumption that the public concedes the right and to make it inequitable thereafter to dispute it." 269 F. at page 211.

Plaintiff in the above case had its product upon the market for only a few months before suit was brought. The court held that insufficient time had elapsed for the product to become identified with the plaintiff. This situation is not comparable with the facts in the case before us because plaintiff's tablet in its distinctive appearance had been on the market for many years before defendants entered the scene. The evidence showed that plaintiff's tablet was identified by many of its doctor users by its distinctive appearance.

"Phenolax Wafers" were sold directly to the public in different packages bearing the names of their respective makers. This again is a situation that is not analogous to the facts in our case where the tablets themselves rarely go

to the ultimate user in the packages of their makers but rather in the packages of the dispensing doctors or druggists.

The court in the Upjohn case declared that the facts were "close to the line." We believe that the distinctions in this case take it out of the decision in the Upjohn case.

The defendants contend that there is no merit in the plaintiff's claim of unfair competition in the manufacture and sale of scored tablets of dosage in the amounts of 5 and 10 milligrams. They assert that scored tablets have been commonly used in the industry for a long period of time, and showed prior use of the cross scored tablets in at least 2 instances in this product, Belladanal and that of the Ciba Company. They offered evidence to show that the manufacturers of the hobs from which the punches and dies are made had manufactured such machines prior to the use by defendants of their double scoring. The defendants argued that their first double scored tablets were produced from double scored punches owned and used by their predecessors in business, the Standard Medical Laboratories. They discarded their first double scored tablet in favor of its successor because the scoring on the first tablet was not deep enough to permit easy and accurate breakage of the tablet. They justified other aspects of the similar appearance of their tablets to the plaintiff's and declared that in none could the plaintiff claim a monopoly. They asserted that the size of the tablet was appropriate because it had to be small enough to be swallowed and large enough to permit it to be broken. They chose the round tablets because in the tableting process that shape could be more readily made than square or irregular shapes could be turned out. They chose the same bevelling and concavity of the bottom of the tablets to prevent crumbling and chipping of edges.

Defendants contend that the combination of features employed by the plaintiff in its tablet entitled it to no exclusive use because the features were purely functional in purpose. Defendants submit that if their tablets were

entirely different from plaintiff's in shape and form it would still be possible for druggists to continue substituting their product for plaintiff's. Because of the small gain involved, defendants scout the idea that druggists would substitute part of a filling of a prescription for 12 tablets. They argued that no intelligent person would resort to such practice because of the small amount of gain to be realized.

They emphasize that there has been no evidence to link the defendants with any alleged substitution other than their manufacture of the tablets and no evidence to indicate that they encouraged or abetted the substitution. They refer to other companies which were similarly manufacturing tablets.

The defendants insist that the testimony of witnesses and employees of the plaintiffs, in identifying tablets and distinguishing them as the plaintiff's product or other than the plaintiff's product, was of little value, particularly because the containers of specimens purchased were kept unsealed in the control of the plaintiff.

The defendants argue that there was no proof that the appearance of the scored tablets of the plaintiff was exclusive with it.

***1008** Morris planned the idea of embarking in the business of supplying amphetamine sulfate tablets and in the absence of patent or other protection he would be free to compete on a fair basis with the plaintiff or anyone else in such a business.

We are confronted with the necessity of determining whether Morris's business enterprise was a fair one to the plaintiff and to the public which has an interest in receiving the very item it desires to purchase.

Morris was a druggist, but in 1938 or 1939 he decided to enter the employ of Squibb as one of its salesmen. In 1941 he determined to engage in the pharmaceutical supply business himself. With his training as a retail druggist

and his experience as a salesman for Squibb in the wholesale field he had a thorough grounding in the fundamentals of his contemplated business venture and was keenly conscious of all of its implications. He knew that plaintiff had singly exploited the sale of amphetamine sulfate under a patent grant and that it had been highly successful in making profits therefrom. He knew of the large circulation of advertising that plaintiff had given to the product. He determined to launch himself into the same field of activity.

The corporation of Clark & Clark was formed while he was still an employee of Squibb. It purchased the necessary machinery and equipment for making tablets from the Standard Medical Laboratories and took up its business at the same address of its predecessor, 417 Mickle Street, Camden, New Jersey. Clark & Clark used this machinery to make amphetamine sulfate tablets. These tablets were shallow cross marked across their faces and were otherwise different from plaintiff's.

Later on, while still in the employ of Squibb, Morris, through his contact with Cusamano, became acquainted with another tablet of amphetamine sulfate, having more nearly the appearance of the plaintiff's. He also came into possession of Cusamano's punches and dies because Clark & Clark undertook to make tablets for Cusamano from these punches and dies.

Morris found encouragement in his project when he was advised that his employer, Squibb, thought little of the plaintiff's patent. This was when he sought to induce Squibb to enter the amphetamine sulfate tablet business, but which Squibb declined. Later his relationship with Squibb was severed and he devoted himself entirely to the exploitation of the amphetamine sulfate tablet business.

He employed Benjamin Zirin, an associate of Cusamano, who was familiar with the sale of the Cusamano tablet, under the name of Custazan, and vigorously prosecuted the sale of the amphetamine sulfate tablets.

His selection of the appearance of the Clark & Clark tablet was unquestionably moved by his desire to make a tablet that would look as nearly like the product of the plaintiff as possible. As a druggist and salesman of pharmaceutical supplies wholesale, he had peculiar knowledge that in placing the product in the hands of druggists there would be no necessity for him to actively encourage substitution by druggists. He realized full well that the product would be unidentified to either the doctor or the patient except for its naked appearance in the package dispensed by the druggist.

Morris does not inspire confidence in his statements or business integrity.

Many contradictions were brought out between his testimony taken in depositions and interrogatories before the trial and that given at the trial. On direct examination he testified that he left Squibb of his own volition but changed that testimony on cross-examination to the effect that he left by reason of a mutual understanding whereby he was asked to resign and resigned simultaneously.

He admitted that he made tablets while he was still employed by Squibb, but he categorically stated that he never made any pharmaceutical product or drug which Squibb was selling or had on the market. However, the plaintiff produced in evidence a product put out by Clark & Clark under the name of Clarsulfetamine which is the identical product as that put out by Squibb under the name of Sulmefrin. The label and the words which appear thereon are identical, with the exception of the name of the product and the manufacturer.

Morris was guilty of many inconsistencies in his testimony. At one time he stated that he had nothing whatsoever to do with the Lannett deal but that his brother handled that matter entirely. At another point in his testimony he

stated that his brother had left Clark & Clark at a time before the Lannett deal took place. This discrepancy was never cleared up.

***1009** Although several different types and brands of pharmaceutical tablets claimed to be similar to the plaintiff's tablet were introduced by the defendants and identified by Morris, when pressed upon cross-examination he was unable to tell the dates when these tablets were put on the market; that is, whether they were on the market as of the date when he manufactured his amphetamine sulfate tablet.

Morris admitted that all other 5 milligram tablets in evidence were not similar to the Smith, Kline & French 5 milligram tablet, and then insisted that a single scored Ascorbic Acid tablet put out by Squibb was similar. He later brought forth a tablet containing Nicotinamide Acid manufactured by Abbott with a single score, which he claimed was confusingly similar to plaintiff's tablet. He then stated that the Squibb Ascorbic Acid tablet was only similar but could not be said to be confusingly similar. A comparison of these tablets with the naked eye convinces us that they are quite dissimilar from the plaintiff's tablet and from each other.

The 5-milligram tablets of amphetamine sulfate produced by Clark & Clark differ in some degree from those of the plaintiff's when they are compared side by side. Noticeably the tablet of the plaintiff is larger in circumference and the groove in the Clark & Clark tablet is wider. Little proof was offered concerning the extent of the traffic in the tablets of this size by either party. However, the general scheme of defendants is such that in the over-all picture the relatively slight differences between the five milligram amphetamine sulfate tablets becomes unimportant.

Various double-scored tablets were produced by the defendants to show confusing similarity with the plaintiff's 10 milligram tablets. These tablets are 1½-grain Phenobarbital manufactured by Yates Drug Company; Fever

No. 2 by the same company; Thiamine Hydrochloride by Abbott and the "Ciba" Dial tablet by the Ciba Pharmaceutical Products Company. None of these tablets can be said to be similar to the plaintiff's 10-milligram amphetamine sulfate tablet.

Several doctors and druggists testified that they identified plaintiff's product by the distinctiveness of its tablet and that they could not distinguish defendants' tablet from the plaintiff's tablet.

One of the points emphasized by Morris was that the consuming public was greatly benefited by the sale of the Clark & Clark tablet because its price was so considerably lower than that of the plaintiff's tablet. He then, however, admitted that the benefits were absorbed before they reached the patient because he never sold his product to the ultimate consumer but only to the distributor, druggist or doctor.

The size, the shape, the depth of the crossed grooves, the bevels, the concavity of the defendants' 10 milligram amphetamine sulfate tablet are as near the counterparts of the plaintiff's product as defendants could make them. The reason for the similarity was because defendants wanted them to be confusingly similar with plaintiff's. It was only with such a product that the defendants could ride upon the vehicle of information, advertising and reputation built up by the plaintiff over the years before defendants thought of entering the field. It was only with such complete similarity and a sales price beneath that of the plaintiff that defendants could readily displace the product of the plaintiff and reap the fruits planted and tended by the plaintiff.

The imitation facilitated the act of substitution. The complete similarity made it easy to pass off the Clark & Clark tablet as the plaintiff's. There was no necessity for any suggestion toward substitution by defendants. The similarity of the tablets was auto suggestive.

There is no question but that tablets had been produced before the plaintiff's, which were double scored and single scored. It is also true that the evidence disclosed that the scoring was generally believed to be present for the purpose of breaking the tablet into segments for smaller dosage than the whole. The depth of the groove, as it generally appears in tablets, does not make a great deal of difference when the tablet is broken by hand. It would appear that the lines or grooves are present as guides rather than as guarantees that the hand pressure will cause completely accurate breakage. Granted that the grooves and all the other features asserted by the defendants were functional in their totality, they gave to the plaintiff's tablet a distinctive appearance. Defendants could have achieved the same functional advantages without copying the plaintiff's tablet. They chose, however, to completely duplicate it ***1010** so that doctors and druggists assumed to be familiar with the product agreed that the tablets were similar.

The evidence was convincing that the substitutions were carried out. A substantial number were proved in court. A variety of drugstores were "shopped" in numerous neighborhoods. The incidents were not isolated or likely to be accidents or coincidences. The plaintiff's witnesses in this regard although employed by it withstood every attack upon their credibility and gave convincing testimony. They appear to be thoroughly reliable and it is hardly likely that they committed substantial mistakes or perjury. Besides which the appearance of the tablets is susceptible of examination and observation by the naked eye and reading glass, and one can readily acquire the ability to make such examination without being an expert in the art.

Of all the numerous tablets offered by defendants not one was similar to the tablet of the plaintiff, certainly not to the point of being susceptible of confusion with it. Each, of course, was a completely foreign substance to that of the tablets in issue here.

The matter of the Pennsylvania Formulary does not bring into direct impact the defendants and the plaintiff or their respective products. However, it lights the activity of the defendants' business practices. There can be no doubt that the device was conceived by Herting and Morris for the purpose of giving endorsement to the Clark & Clark product, as produced under the authority of the responsible Joint Committee of the two organizations representing respectively the doctors and druggists of the State of Pennsylvania. It was a bold attempt to impose upon the organizations and the general public and completely indicative of a total lack of good faith and fair dealing.

The misrepresentations made in the letters forwarded by Morris for the defendant Clark & Clark again do not impinge directly upon the plaintiff. They do, however, demonstrate how far he was willing to deviate from the straight line of candor and square business dealing.

In these last instances Morris was disclosed to be a high pressure promoter willing to go far beyond the legitimate "puffing" of his wares and trespass deep into the area of misrepresentation and deceit in order to accomplish his one and main objective namely, the sale of amphetamine sulfate.

The light those instances cast upon the designed imitation of plaintiff's product and the proven practices of substitution compel inevitably the decision that defendants are guilty of unfair competition as charged by the plaintiff.

B. Defendants' Charges of Unfair Competitive Practices

The defendants have filed a counterclaim alleging injuries to their business as a result of the unfair business practices of the plaintiff. Their claim of injury appears to fall into three categories: (1) Damages arising from notices

sent to the trade and threats made to suppliers and distributors informing them of the patent rights of the plaintiff; (2) damages arising from plaintiff's interference with defendants' channel of distribution of amphetamine sulfate by means of the Pennsylvania Formulary which they allege resulted in its withdrawal; and (3) that plaintiff deliberately refused to sell milk sugar which was necessary to the completion of defendants' government contracts and for the manufacture of amphetamine sulfate by the corporate defendant and consequently forced it to get its supply elsewhere.

In support of the defendants' submission under point 1, the following letter was offered in evidence:

"Smith, Kline & French Laboratories "Philadelphia "October 26, 1943 "Important Notice "Benzedrine Sulfate

"Entirely erroneous information appears to have been recently circulated to the Drug Trade concerning the patent status of amphetamine sulfate.

"As you know, this drug is manufactured and distributed by us under our registered trade name `Benzedrine Sulfate', and, through the research and development work we have carried on for many years, it has become widely accepted by the medical profession both in the United States and in foreign countries.

"Smith, Kline & French Laboratories holds United States Letters Patent No. 1,879,003, covering this drug for its recognized medicinal uses. The patent was issued in 1932; was assigned to us in 1934; *and will not expire until 1949.* We have ***1011** not granted a license to anyone to manufacture amphetamine sulfate, with the one exception that we have licensed its manufacture for veterinary use only to the Pitman-Moore Company of Indianapolis.

"Our patent rights have never been successfully attacked in any Court nor have they been in any way modified, cancelled or annulled by the United States Patent Office. Without exception, *these rights have been respected by every pharmaceutical manufacturer of national importance.*

"However, as so frequently happens with a successful preparation, there are those who seek to capitalize on the work of others, and we have been obliged to institute, and now have pending five suits in the United States courts in Pennsylvania, New York and New Jersey against infringers.

"It is our position that persons manufacturing and persons distributing, at wholesale or retail, amphetamine sulfate for recognized medicinal uses, other than the genuine Benzedrine Sulfate manufactured and distributed by Smith, Kline & French Laboratories, do so in violation of our legal rights, and it is our policy to exercise all rights available to us to prevent such practice.

"For your own protection, order, sell and handle only genuine Benzedrine Sulfate.

"Smith, Kline & French Laboratories "(Signed) O. J. May "L:BS Vice-President"

This notice is within the limits of good faith allowed one who seeks to protect his patent rights. Plaintiff had a right to rely upon the validity of its patent when issued by the Patent Office so long as its methods were in good faith. The material contained in plaintiff's notices and the oral statements made by its representatives to those whom it had reason to believe were infringing upon its rights were made in accordance with the truth. In its reference to holding a patent covering the drug "for its recognized medicinal purposes" the plaintiff did not overstep the proprieties of such notice. The known uses of the drug were in the field of medicine as it affected the human central and sympathetic nervous systems as the salt of ephedrine

affected those systems. There is no evidence to show that it acted from any other motive than to protect what it believed to be its rights based upon a presumption of patent validity and no bad faith was shown.

Its dealings with Commercial Solvents Corporation and Northern States Trading Corporation, alleged by Clark & Clark to be its source of supply, and with Samuel P. Sadtler & Sons, Inc., alleged by the corporate defendant to have contracted with Clark & Clark for the synthesis of amphetamine sulfate and which contract was withdrawn, fall within the methods permissible for protection and without the area of bad faith. This is also true with respect to the evidence with reference to the negotiations of plaintiff with certain distributors of amphetamine sulfate tablets. The fact that Commercial Solvents sold the base of the salt alone and that Northern States Trading Corporation sold the salt only in bulk form, does not alter the rights of the plaintiff to protect its patent in good faith by giving them reasonable notice of its conception of its rights. If these concerns believed that they had the justifiable defenses that the defendants claimed for them with respect to their sale of amphetamine sulfate in a manner not encompassed by the claims of the patent, they were free to assert them in legal action. Apparently they were not convinced that they could support such views.

The evidence shows that the objections made by the plaintiff to the Committee of the Pennsylvania Formulary certainly fell short of justifiable complaint. This is evidenced by the other objections made to the Formulary as set forth in its ultimate withdrawal.

The facts with regard to the delivery and sale of milk sugar by the plaintiff to Clark & Clark are clearly defined in the evidence and fail to support in any respect the view that the corporate defendant takes under point 3 that the plaintiff refused to sell milk sugar for any reason whatsoever.

On March 24, 1942, the plaintiff and Clark & Clark entered into a written agreement whereby the plaintiff contracted to sell to Clark & Clark 10 barrels of 200 pounds each of milk sugar at 26 cents per pound, delivered, cash with order, within a period of one year, to be delivered in approximately equal monthly or quarterly installments.

On March 24, 1942, Clark & Clark ordered one barrel of milk sugar. It was delivered by plaintiff on March 26, 1942.

On June 3, 1942, Clark & Clark ordered another barrel of milk sugar which was delivered on June 5, 1942. The check plaintiff ***1012** received for this latter barrel was returned by the bank for "Insufficient Funds." It was redeposited and then paid.

On June 25, 1942, Clark & Clark ordered a barrel of milk sugar which was shipped the same date with the invoice noted "Accept company check only."

On July 8, 1942, an order was given for one barrel of milk sugar. It was not paid for when delivered on July 10, 1942, and was returned to the plaintiff who again attempted a delivery on July 14, 1942. This barrel was not paid for on that date and plaintiff's driver returned it to its plant.

Subsequent to this attempted delivery the plaintiff received calls from Clark & Clark and the War Production Board which both stated that Clark & Clark had been working on a government contract and had a priority for the milk sugar. The plaintiff informed both parties that the milk sugar was ready for Morris as soon as it received the cash for it. Morris came down to plaintiff's place of business on July 15, 1942, paid cash for the single barrel of milk sugar and presented an order, together with a priority, for two additional barrels. He paid cash for the latter two barrels which were delivered on July 15th and 17th as per the agreement between the parties.

On July 30, 1942, an order for two barrels of milk sugar was received by plaintiff through the mail with a check enclosed. This order and the check were returned for the reason that the contract called for deliveries "in approximately equal monthly or quarterly installments." Only slightly more than four months of the contract period had elapsed but Morris had already received more than one-half of the total amount of milk sugar to which he was entitled under it.

On February 25, 1943, an order for five barrels of milk sugar, together with a check for the same, was received by plaintiff. It reported to Clark & Clark, stating that it was only entitled to 2½ barrels for the quarter ending March 24, 1943, but that it would sell Clark & Clark three barrels under the contract. This order was made on March 16, 1943, and delivery of the three barrels was made on March 19, 1943.

The contract for milk sugar expired on March 24, 1943, and was not renewed. At the date of the trial there existed a shortage in the material which is under strict government supervision.

This evidence distinctly shows that at no time did plaintiff refuse to deliver milk sugar to Clark & Clark without reasonable justification.

Its action in requesting cash or a company check subsequent to the receipt of the check in payment of a barrel of milk sugar marked "Insufficient Funds" was reasonable and justifiable business practice. It lived up to the terms of its contract in every respect.

The counterclaim will be denied.

Accordingly we hold Letters Patent No. 1,879,003 of the plaintiff valid and infringed; that the defendants are guilty of unfair competition as charged by plaintiff and that their counterclaim for damages for unfair competitive practices upon the part of the plaintiff should be dismissed.

A decree should be settled providing for the relief sought by the plaintiff.

NOTES

[1] A phase of the point of view in the Potts case is expressed by the court as follows:

"In determining whether an invention has been made the character of the article or process, its novelty, and its advance over the prior art are merely evidentiary. The ultimate question is the character of the contribution made by the inventor. There is no invention without inventive genius. The objective advance does not identify or evaluate the individual achievement. The individual achievement is becoming more and more difficult to identify and evaluate as organized research becomes our greatest source of invention. And so the trend of recent decisions has been to emphasize more and more the character of the individual achievement rather than the qualities of the product in determining patentability. We have held that a step forward which, considered in connection with the highly developed condition of the art, might reasonably be expected from the research of highly trained specialists is not invention. Thus neither the result of great industry in experimental research nor the successful product of a gradual process of experimentation over a period is invention. Routineering, even by the most highly trained specialists, step by step improvements, the carrying forward of a new and more extended application of the art, are not invention.

"In order to evaluate the contribution of the inventor the court must reconstruct the conditions under which he worked, with emphasis on the contribution of others. This method is sharply outlined in the case of Marconi Wireless Telegraph Co. v. United States [320 U.S. 1, 63 S. Ct. 1393, 87 L. Ed. 1731], because a different point of view was there considered and rejected by the Supreme Court. In his dissenting opinion Mr. Justice Frankfurter argued that inventions have always been `parts of an

evolution, the culmination at a particular moment of an antecedent process.' He asserts that the majority was wrong in using `reconstruction by hindsight' of the state of the art in such a way as to show that the final step made by Marconi was one which could have been made by an ordinary expert of high skill. He objects to the process by which `a judge of unusual capacity for understanding scientific matters is, by a process of intricate ratiocination, able to demonstrate that anyone could have drawn precisely the inferences that Marconi does * * *.' He repudiates the flash of genius doctrine which depends entirely upon an evaluation of individual accomplishment. Nowhere is this point of view better stated. Yet the Court declined to accept it. Both the majority opinion, declaring the patent in question invalid, and Mr. Justice Rutledge, in a separate dissent, are concerned only with an evaluation of the individual achievement of Marconi, considered in connection with the accomplishment of others in the field.

"In other words, patents are not intended as a reward for a highly skilled scientist who completes the final step in a technique, standing on the shoulders of others who have gone before him. By the same token they are not intended as a reward for the collective achievement of a corporate research organization. Today routine experimentation in the great corporate laboratories can produce results beyond the imagination of twenty years ago. But such contributions to industrial art are more often than not the step by step progress of an entire group, not the achievement of an individual. Such an advance is the product not of inventive ability but of the financial resources and organizing ability of those who operate the laboratories. The practice of requiring the expert employees of research organizations to assign in advance all their future patent rights to the organization, itself reflects the respective contributions of the organization and the individual to these so-called inventions. The `inventor' is paid only a salary, he gets no royalties, he has no property rights in the improvements which he helps to create.

"To give patents for such routine experimentation on a vast scale is to use the patent law to reward capital investment, and create monopolies for corporate organizers instead of men of inventive genius." 78 U.S.App.D.C. at pages 299-301, 140 F.2d at pages 472-474.

Also see opinion on rehearing reported in 79 U.S.App.D.C. 223, 145 F.2d 27.

For a point of view other than that expressed in the Potts case, see the opinion of the court in Dennis v. Pitner, 7 Cir., 106 F.2d 142, at pages 144, 145, certiorari denied 308 U.S. 606, 60 S. Ct. 143, 84 L. Ed. 507, wherein it is stated:

"We believe it to be a sound pronouncement to say the discovery of a natural phenomenon, or of a quality or attribute of a well-known article, which discovery is of value to mankind, may be entitled to patent protection. The objection frequently offered to the patentability of such a discovery is that it is a law of nature or a principle of nature and for that reason not patentable. Section 31, Title 35, U.S. C.A., authorizes the issuance of a patent to

"`Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof * * * not known or used by others in this country, before his invention or discovery thereof, and not patented or described in any printed publication in this or any foreign country, before his invention or discovery thereof * * *.'

"There would seem to be no valid reason or sound support for a position which would deny to discoveries by researchers in the field of science the protection of our patent laws when such discovery is that an old, or at least well-known chemical product, will, acting in a given state, alone, or combined with other elements or physical elements, produce new, unknown, and unexpected results, where as one who puts together at least two old and

well-known chemical substances in certain prescribed proportions and gets new results helpful to man may receive patent protection. In the latter case, patent protection is universally accorded to the discovery.

"In both cases it must be and is assumed, of course, that the discoverer is first, that he timely files his application, and that his said discovery is `new and useful,' and was not the result of the exercise of ordinary mechanical skill or the fruit of the reasoning of the normal individual skilled in the art wherein the invention lies.

"It would seem to be an unjustifiable distinction to recognize as patentable a machine or other product which puts into novel combination a plurality of old elements producing a new and useful article, and deny to one working in a research field the protection of his discovery, because in his search he finds that a certain article, which we will call a chemical, will act, when taken into the human system or applied to the earth or upon some mineral found therein, in a beneficial way hitherto unknown to man. Clearly the patent law was enacted to benefit society by encouraging discoveries and inventions. That is accomplished by the Government's giving to the inventor or discoverer a patent a legal monopoly for a term of years.

"An analysis of the essential parts of the statute is illuminating. Congress provided for the granting of patents to (a) any person, (b) who has invented or discovered, (c) any new and useful, (d) art, machine, manufacture, or composition of matter, (e) or any new and useful improvements thereof, (f) not known or used by others in this country, (g) before his invention or discovery, (h) and not patented or described in any printed publication in this or any foreign country, (i) before his invention or discovery thereof, etc.

"Emphasis must be placed upon the words `invented or discovered' `new and useful' `art, machine, manufacture, or composition of matter.'

"It is true that an old substance with newly discovered qualities possessed those qualities before the discovery was made. But it is a refinement of distinction both illogical and unjustifiable and destructive of the laudable object of the statute to award a patent to one who puts old ingredient A with old ingredient B and produces a cure for ailment C, and deny patent protection to one who discovers that a simple and unadulterated or unmodified root or herb, or a chemical has ingredients or health-giving qualities, hitherto unknown and unforeseen."