20727. Alleged misbranding of Banbar. U. S. v. Leo Banks Barlett. Tried to a jury. Verdict of not guilty. (F. & D. no. 27458. I. S. no. 5604.)

On January 28, 1932, the United States attorney for the Western District of Pennsylvania, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid an information against Leo Banks Barlett, Pittsburgh, Pa., charging shipment by said defendant in violation of the Food and Drugs Act as amended, on or about February 12, 1931, from the State of Pennsylvania into the State of New York, of a quantity of Banbar. The article was labeled in part: "Banbar, * * * For the Diabetic * * * Diabetes Mellitus. * * * distributed only by L. B. Barlett * * * Pittsburgh, Pa."

Analysis of a sample of the article by this Department showed that it consisted essentially of magnesium sulphate, potassium acetate, extracts of plant drugs including equisetum, uva ursi, podophyllum, nux vomica and leptandra, alcohol, and water.

The information alleged that the article was misbranded in that certain statements, designs, and devices regarding the curative and therapeutic effects of the article, appearing on the bottle label, falsely and fraudulently represented that it was effective as a treatment for the diabetic and effective as a treatment, remedy, and cure for diabetes mellitus.

The defendant entered a plea of not guilty to the information, and the case came on for trial before a jury on February 27, 1933. Evidence of lay witnesses and expert medical testimony was introduced by the Government in support of its contentions. The trail was concluded on March 8, 1933, on which date closing arguments were made by counsel and the following instructions delivered to the jury by the court (Gibson, *J.*):

"Gentlemen of the jury: You have been sworn to try the issues of fact raised by an information filed on behalf of the United States against the defendant, Leo Banks Barlett. That information has been drawn under a Federal statute which prohibits under penalty the transportation of misbranded articles of food or of drugs from one State to another. Under statute, the term 'drug', as used in the statute, includes 'all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either men or other animals.' It has defined the misbranding which is prohibited in connection with the transportation of food or drugs from one State to another, for the purposes of certain sections of the act, that is, in regard to false statements with respect to curative or therapeutic effect: 'An article shall be deemed to be misbranded if its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein which is false and fraudulent.'

"Before discussing the specific issues raised by the information, I desire to call your attention to certain general principles to be remembered by you in the performance of your duty. It will be your duty to accept propositions of law as laid down to you by the court. That duty, however, does not extend to matters of fact. It is the peculiar function of the jury to recollect the testimony and to determine what matters of fact have been established by it. It is not the function of the court to express any opinion in regard to matters of fact established by the testimony in this case; but if inadvertently we should do so, you will recollect that you are not to be controlled by any opinion of the court as to matters of fact or as to recollection of the testimony, but it will be your duty to follow your own recollection and your own findings of fact. It follows from your duty of determining the facts that you are called upon to determine the credibility of the witnesses, that is, the effect which is to be given to any testimony given by any witness produced before you. You should not attribute willful false swearing, perjury, to any witness or set of witnesses where there is difference in the testimony of witnesses, but should reconcile the testimony, if it is possible, without attributing perjury to either witness or set of witnesses; if that reconciliation be impossible, it is your duty to determine which witnesses are telling that which is false and which are telling that which is true. But under the circumstances, it is your duty to weigh the testimony of each witness and determine its weight. In testing a witness and determining the weight of his credibility, you may apply any test you may deem proper. It is always proper to consider the manner and appearance of the witness upon the stand, the opportunity which

he may have had to know in regard to the subject matter of his testimony, the consistency of his story, both considered from the one part of his testimony as against the other, and as compared with the testimony of other witnesses whom you deem to be credible.

"This is a charge which carries with it a penalty upon conviction, and in such case the defendant at the inception of the case is presumed to be innocent, and that presumption remains with him throughout the trial until it has been overthrown by the testimony introduced on behalf of the Government. To overthrow that presumption the burden of proof is on the Government. It must produce proof which is sufficient to satisfy you beyond a reasonable doubt of the offense which is charged in the information or indictment against the defendant. A reasonable doubt is not one conjured up or obtained from any other source than the evidence introduced before you. If, after a fair and full consideration of the evidence introduced, your minds are left uncertain, you have no fixed opinion as to the guilt of the defendant under the charge of the information, then you have a reasonable doubt, which is the property of the defendant, and which must lead to his acquittal. On the other hand, if the evidence, and the evidence alone considered, is such as to give you a fixed opinion as to his guilt, then the reverse is true, and you have no reasonable doubt which should lead to the acquittal, but your verdict should be one of conviction.

"Coming then to the charges of the information, we find that substantially four particular facts must be established beyond a reasonable doubt by the Government, before a verdict of guilty may be returned by you. First, the Government is called upon under the pleadings here to establish that this defendant transported or caused to be transported and consigned to one Miss Florence J. Edwards a certain bottle, from the State of Pennsylvania to the consignee in the State of New York. As to the fact of the shipment of a bottle with its contents, known as Banbar, by this defendant, the Government has introduced proof as to the shipment from Pittsburgh and the receipt in Buffalo, I believe, in the State of New York, by Miss Edwards, of a certain bottle; and as to the shipment of that bottle, the defendant has introduced no testimony in denial, and has either directly or inferentially admitted the shipment, as the court recollects. It will be for you to determine.

"The second step of the determination of the issue involved here is whether or not, also, that bottle contained or had thereon a label which set out a statement that the contents of the bottle were intended for the cure, mitigation, or prevention of diabetes. The Government has introduced in evidence a certain label which its testimony proves, it asserts, was upon the bottle shipped by the defendant to Miss Edwards on the day and date charged in the information. That label does not contain a direct allegation that the contents of the bottle possessed any curative or beneficial effect, but it does state that it is 'for the diabetic.' Now, in order to constitute a branding which is contrary to the statute, it is not necessary that such direct, specific claim be placed upon the bottle. If the branding, the labeling of the bottle, is such as would influence anyone to whom it came, or who was looking at it, to believe that it was held out as a cure or a medicine which would be beneficial in the use of any particular disease, then that phase of the matter has been sufficiently taken care of. Now, in this matter of the branding, as we understand it, the defendant—as in the transportation of the package—has not made any claim to the effect that this particular branding, this label upon the bottle, does not set forth a branding which is contemplated by the statute; in other words, in argument before you and in the taking of the testimony, as the court recollects it, the defendant has assumed that the bottle did set forth upon its label a brand which was sufficient to convince the person seeing it that the contents of the bottle were held out as a medicine which was of benefit in the treatment of diabetes.

"The next point of fact for your determination, however, is one which is in serious controversy in this particular case. The charge in the information is that the label was false and misleading, (sic) because the product in the bottle was actually useless and of no effect, and that it had no power to cure or mitigate or prevent diabetes. The Government has offered evidence which it claims establishes that particular fact; and in turn the defendant has offered evidence which he claims controverts that claim and establishes that this particular medicine was of value. It is not claimed by the defendant that it is an absolute cure, of all cases, at least, of diabetes, but the defendant asserts that his evidence establishes the fact that the medicine which is

put out under this name of 'Banbar' is of therapeutic value, that is, that it will at least aid and be of benefit in the treatment of diabetes.

"If you have been satisfied beyond a reasonable doubt of the fact that the bottle charged in the information was transported or caused to be transported by the defendant from Pittsburgh to Buffalo, as charged, from one State to another, that it contained or had thereon affixed a label which set forth a product as beneficial in the treatment of diabetes, you will then proceed to take a further step in your inquiry. It you have not been so satisfied, you need proceed no further, and it will be your duty to return a verdict of not guilty as to the defendant. But if so satisfied, you will proceed to the next step, which is to determine whether or not the bottle and the product within it, branded as set forth, was put into interstate commerce by the defendant falsely and fraudulently, that is, with knowledge that the contents of the bottle were of no value whatsoever in the treatment of diabetes and for diabetics, and with that knowledge sent out by him, with the intent of deceiving a purchaser and with the intent of getting his money without rendering him anything of value therefor. To amplify upon what I have just said: The matter for decision in this case it not entirely whether or not this particular product, 'Banbar', is beneficial for treatment of diabetes. The knowledge and intent of this defendant must be fraudulent, that is, his act must be a fraudulent act. The Government is called upon to establish here that he either knew that this product was absolutely worthless, or that he willfully and wantonly failed to inquire or acquaint himself with the value or lack of value of the product, and sent it out with entire lack of knowledge as to its quality, with the intent of getting the money of the person to whom it was sent or who might seek to buy it, without any regard to its efficacy for the purposes for which it was held out; and even if you should find, therefore, that the product was worthless in the treatment of diabetes, before you may return a verdict of guilty under the information, it will be necessary for you to be satisfied beyond a reasonable doubt that he sent it out with an actually fraudulent intent. In that connection, you will consider, of course, all the testimony which will throw light or tend to throw light upon his mental state in sending out the package in question. The charge in the information is not that the defendant's product was not made pursuant to proper and scientific methods of investigation and test, or that it was not scientifically tested before it was put out, but that the defendant put it out with a fraudulent intent. No matter how ignorant he may have been, or how unscientific or even careless his methods, such ignorance or lack of proper methods is not the charge of the information.

"If you have been satisfied beyond a reasonable doubt that this package was consigned from Pittsburgh to Buffalo, to the person named in the information, as charged; that it contained a label which was false and misleading, in that it set forth that the contents were of value in the treatment of diabetes; that the contents, the product in the bottle, was of no medicinal value for the purpose for which it was held out, and that the defendant knew that it was so worthless, or had no reason to believe that it was of any virtue in the treatment of diabetes, but did so send it with the intent of defrauding any person who might purchase it or obtain it, then it would be your duty to return a verdict of guilty as charged in the information; if you have not been so satisfied, it will be your duty to return a verdict of not guilty.

"Now, this case has been tried, gentlemen of the jury, by the counsel on each side with meticulous care, and it is not my purpose to amplify upon the evidence which they have reviewed before you. You will keep in mind the Government has introduced testimony which it claims establishes all of the matters which are essential to the return of a verdict of guilty; the defendant has introduced testimony, on the other side, which it alleges controverts these particular claims. The Government has introduced, by witnesses called before you, chemists who have analyzed the contents of the medicine, has also introduced physicians and other experts, the effect of whose testimony, it contends, is that the contents of the bottle was of no curative value whatsoever, and also medical witnesses who have testified that the consensus of medical opinion is that no drug or material other than insulin is of any value in the direct treatment of diabetes. It has also introduced a number of witnesses, each of whom stated that he or she had made use of or had used for a time the particular product put out by the defendant, and that no benefit whatsoever was received from its use. The defendant, on the other hand, has introduced the evidence of chemists which to some extent contradicts the testimony offered by the Government by

means of chemists put upon the stand by it. The Government contends that the actual product put out by the defendant was not exactly as stated. However, that may be somewhat immaterial, because both sets of witnesses—that is, both sets of chemical witnesses, if we may call them so—agree that a component of the product was a certain herb known as horsetail, or equisetum, I believe, is the botanical name for it, and it is claimed on behalf of the defendant that that is the actual active part of the product. The defendant has also introduced certain physicians who have made use of this product in their practice and allege that it does have some therapeutic value. And the defendant also has introduced a number of users of the defendant's product, who assert that they have received considerable help in the treatment of diabetes by means of the drug.

"To repeat: If you are satisfied beyond a reasonable doubt as to the consignment in interstate commerce of the bottle charged, that it was branded as charged, that the product was of no value whatsoever in the treatment of diabetes, and that it was sent out by the defendant knowing that the branding of the bottle was false and misleading, and that he had the actual intent to defraud in sending it out, it would be your duty to return a verdict of guilty under the information; and if you are not so satisfied beyond a reasonable doubt as to either the consignment in interstate commerce, the branding of the bottle, the value of the product in the treatment of diabetes, or as to the fraudulent intent of the defendant, it will be your duty to return a verdict of not guilty.

"I neglected to call your attention to certain evidence introduced on behalf of the defendant. He has called here several witnesses who have testified to his good reputation in the community wherein he dwelt. That is substantive testimony, gentlemen of the jury, and it will be your duty to consider it in connection with all the other testimony in the case, and give it such weight as you deem proper.

"The defendant has submitted to me certain points. The first and second points are denied, and not read. An exception is noted to the defendant.

"The third point: 'That if the jury believes that the defendant has received a large number of testimonials from individuals and from medical doctors to the effect that the remedy "Banbar" had helped them in their diabetic ailment, and if the jury further believes that the defendant relied upon these testimonials, then the defendant should be acquitted.' That is rather a general declaration. However, we affirm it, gentlemen of the jury; you will consider it in connection with our comments upon the charge that the defendant had falsely and fraudulently put out this package with the label, that is, put out the package with the false and fraudulent label.

"Has there been any omission?"

Mr. Bryan: If the court please, I would like to have an exception to that last point.

The Court: I am afraid an exception won't do the Government much good in a criminal case. However, I will give you one.

Mr. Bryan: I would like to have the court charge, as laid down in the Supreme Court case,—I will hand this to the court (handing paper to court).

The Court: This is in a shape, Mr. Bryan, I cannot tell what you want; and I think I have covered the matter in my charge, so I will not charge any further.

The Court (continuing): Gentlemen, you will recollect you have a thirteenth juror, chosen to sit only in the event that something happened so that one or the other of the jurors could not remain. I am glad to say that all of the jurors have been able to sit through the case, so that the case will be considered by the 12 jurors who were first sworn, and the thirteenth juror will not participate in your findings.

Mr. Bryan: I would like to have the court charge that the language used in the label is to be given the meaning ordinarily conveyed by it to those to whom it is addressed.

The Court: I think I have perhaps covered that sufficiently, but I will say to the jury that the language upon the label is to be considered from the viewpoint of those to whom the label comes, or to whose view it comes.

Mr. Bryan: And also, I would like to have the court charge that persons who make or deal in substances or compositions alleged to be curative are in a position to have superior knowledge, and may be held to good faith in their statements.

The Court: Gentlemen, at the request of the United States attorney, I charge you: That persons who make or deal in substances or compositions alleged to be curative are in position to have superior knowledge and may be held to good faith in their statements. I trust that subject matter, in substance, has been set forth to you in the general charge, and that you will understand that the good faith or the reverse of the defendant is in issue in this case.

Mr. Bryan: Also, I think the court overlooked, it is also in the information "with wanton and reckless disregard of the truth or falsity", fraud may be inferred from the circumstances—

The Court: That is not the way to present points, Mr. Bryan. They should be written out and submitted to the court before the charge. I am not going to give the jury any more.

Mr. Bryan: I thought the court would cover those.

The Court: You may take the case, gentlemen of the jury, and render such a verdict as your consciences require.

On March 9, 1933, the jury returned a verdict of not guilty.

R. G. TUGWELL, *Acting Secretary of Agriculture.*

20728. Adulteration and misbranding of tincture of benzoin, lavender oil, sweet almond oil, eucalyptus oil, Carnatine red, Manderine orange, and coumarin; and adulteration of cassia oil, peppermint oil, sandalwood oil, and artificial mustard oil. U. S. v. Edward I. Lowell. Plea of guilty. Fine, $800. (F. & D. no. 26569. I. S. nos. 2435, 3282 to 3289, incl., 3818, 4626, 4628.)

This case was based on the interstate shipment of several products, sold under names recognized in the United States Pharmacopoeia, that differed from the pharmacopoeial requirements; also of food-coloring agents, namely, Carnatine red and Manderine orange shade that contained sugar, and coumarin that contained undeclared acetanilid. The tincture of benzoin contained undeclared alcohol.

On July 21, 1932, the United States attorney for the Southern District of New York, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States an information against Edward I. Lowell, New York, N.Y., charging violation of the Food and Drugs Act. The information charged that the defendant had shipped from the State of New York into the State of New Jersey, on or about August 6, 1930, a quantity of tincture of benzoin that was adulterated; had shipped from New York into the State of Pennsylvania, between the dates of November 16, 1929, and July 22, 1930, quantities of oil lavender, oil sweet almond and oil eucalyptus, which were adulterated and misbranded, and a quantity each of oil cassia, oil peppermint, oil mustard artificial and oil sandalwood which were adulterated; had shipped from New York into South Carolina on or about August 15, 1930, a quantity of Carnatine red that was adulterated and misbranded, and had shipped into the State of Connecticut on or about June 5, and August 13, 1930, quantities of Manderine orange shade and coumarin that were adulterated and misbranded. The articles were labeled: "Edward I. Lowell Importer and Manufacturer * * * 113 Maiden Lane New York."

The information alleged that the tincture benzoin, oil lavender, oil cassia, oil sweet almond, oil eucalyptus, oil peppermint, oil mustard artificial, and oil sandalwood were adulterated in that they were sold under and by names recognized in the United States Pharmacopoeia, and differed from the standard of strength, quality, and purity as determined by the tests laid down in the said pharmacopoeia official at the time of investigation, and their own standards of strength, quality, and purity were not declared on the containers.

Misbranding of the tincture benzoin was alleged for the reason that the statement "Tincture Benzoin", borne on the label, was false and misleading, since it represented that the article consisted wholly of tincture benzoin, whereas it was composed in part of acetone; for the further reason that it was offered for sale under the name of another article; and for the further reason that it contained alcohol and the label failed to bear a statement of the proportion or quantity of alcohol contained therein.

Misbranding of the oil lavender flowers was alleged for the reason that the article was a product composed of oil or oils other than oil lavender flowers, prepared in imitation of oil lavender flowers, and was offered for sale and sold under the name of another article.

Misbranding of the oil sweet almond was alleged for the reason that the statement, "Oil Sweet Almond", borne on the label, was false and misleading, since it represented that the article consisted wholly of oil of sweet almond,