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State of Utah v. Burch-Wood, Ltd. Et al : Brief of Appellant

Utah Supreme Court

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IN THE SUPREME COURT OF THE
STATE OF UTAH

STATE OF UTAH, Department
of Social Services, by and
through the Division of
Health,

Plaintiff-Appellant

-vs-

BURCH-WOOD, LTD., a Utah
Corporation dba Melwood
Steele Centres, Inter-
national, Ltd., LAVOR R.
WOOD, ROBERT L. MONSON,
MELWOOD J. STEELE and
FRANCIS R. SALAZAR,

Defendant-Appellee

CASE NO. 14657

BRIEF OF APPELLANT

APPEAL FROM THE JUDGMENT, FINDINGS OF FACT
AND CONCLUSIONS OF LAW OF THE THIRD JUDICIAL
DISTRICT COURT OF SALT LAKE COUNTY, STATE OF UTAH,
THE HONORABLE STEWART M. HANSEN, SR., JUDGE, PRE-
SIDING.

FILED

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STATE OF UTAH, Department :
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Plaintiff-Appellant :

-vs- :

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Corporation dba Melwood :
Steele Centres, Inter- :
national, Ltd., LAVOR R. :
WOOD, ROBERT L. MONSON, :
MELWOOD J. STEELE and :
FRANCIS R. SALAZAR, :

Defendant-Appelle, :

BRIEF OF APPELLANT

STATEMENT OF THE NATURE OF THE CASE

The petitioner, State of Utah, respectfully ap-
peals from the findings of fact and conclusions of law as
entered and the decision ordered by the Honorable Stewart
M. Hansen, Sr. in the 3rd Judicial District Court of Salt
Lake County, that the temporary injunction against defend-
ants and dismiss the case.

DISPOSITION OF THE LOWER COURT

The District Court concluded that the Plaintiff's Order to Show Cause should be denied, that the temporary restraining order theretofore issued by the court should be dissolved, and that the case should be dismissed without prejudice.

RELIEF SOUGHT ON APPEAL

Appellant respectfully submits that the judgment of the Third Judicial Court of Salt Lake County should be reversed, that the temporary injunction against the defendants be reissued, and that the plaintiff's Order to Show cause be granted.

STATEMENT OF THE FACTS

The plaintiff brought a complaint for temporary injunction against the defendants Burch-Wood, Ltd, to enjoin them from further selling, delivering, offering for sale or giving away any of defendants' substance known as "Melwood Steele Formula" which was being used by defendants in the treatment of male and female pattern baldness (alcopecia and diffuse alopecia) until such time as they complied with the requirements of the Utah Food, Drug and Cosmetic Act, U.C.A. 4-26-18 (as amended) (R-63)

The Third Judicial District Court of Salt Lake County ruled that the "Melwood Steele Formula" was not a drug within the purview of Utah Code Annotated §4-26-2, 3

and 5. The court stated that the use of the substance in question did not affect the structure or any function of the body of man. Hence the Court denied the plaintiff's Order to Show Cause, dissolved the temporary restraining order, and dismissed the case.

Subsequently the findings of fact and conclusions of law were approved by the Court.

ARGUMENT

POINT I

THE DISTRICT COURT ERRED IN APPROVING THE FINDINGS OF FACT AND CONCLUSIONS OF LAW BECAUSE MANY OF THE FINDINGS OF FACTS WERE CLEARLY NOT SUPPORTED BY THE EVIDENCE FROM THE RECORD OR OTHERWISE.

The second findings of fact states that: "The Melwood Steele Formula does not contain articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary or any supplement to any of them." This is an unsubstantiated conclusion on the part of the Court since no evidence was adduced at trial as to what specifically was the composition of the Melwood Steele formula. Melwood J. Steele stated in his affidavit that all the nutrients in the formula are "constituents of food stuffs found in your local supermarket." (R-74) From this we have no clue that certain ingredients weren't recognized in any of the above mentioned journals. There is

simply no evidence upon which to base this finding of fact.

Finding No. 6 is not a finding of fact supported by the evidence from the record. The Melwood Steele Formula was not shown to feed or nourish the hair cell with food or nutrients. In fact the formula's efficiency was not an issue in this case. The purpose of the hearing in the court below was to determine whether the defendants had conformed to the Utah Statutes. It was not to determine whether the formula itself was effective. Certainly the trial court would not attempt to rule that this formula "feeds" and/or "nourishes the hair" as a matter of law.

Finding No. 7 is, in the first portion, a restatement of No. 2 and is objected to for the same reasons as stated above.

Finding No. 11 is in contradiction to the evidence shown at trial. On recross examination, Mr. Blaine A. Goff, coordinator of drugs and cosmetics of the State Division of Health, State of Utah, informed the defendants that they were violating the Utah Food, Drug and Cosmetic Act. (T 30) He also stated in court: "We have asked for an application and there have been numerous requests." (T 43) The only reason that Mr. Goff suggested filing with the Federal Food and Drug Administration was because their requirements are the same as the State requirements and

Federal filing is accepted in Utah in lieu of State filing. Utah Code Annotated, §4-26-18.1 (1). Besides it seemed obvious to the plaintiffs that the defendants were intending to go interstate with their product (T 32). Mr. Goff was simply trying to facilitate the defendant's filing. Mr. Goff also indicated on page 32 of the record: "We have resources available to us from the University of Utah and other experts whom we deal with routinely that would be qualified to review the application." Mr. Arnold J. Peart, employee in the drug and cosmetic compliance department for the Utah State Division of Health, also indicated in his testimony on direct examination that the State of Utah would accept the Federal Government's decision as to the filing (T 27). Utah's Act provides for such filing under Utah Code Annotated §4-26-18.1(1) as amended.

Fact No. 12 is not clear. The record shows that the defendants applied for a ruling from the Federal Food and Drug Administration as to whether their product was a drug. It also shows that they were attempting to find out the requirements for filing (T 33). The defendants received a letter from the Federal Food and Drug Administration concerning that agency's determination of whether the Melwood Steele Formula was a drug (T 34). It appears from an overall reading of entire record that it was only after receiving this letter that the defendants decided not to file federally.

There is no indication from the record or otherwise that the defendants didn't intend to go interstate with their product. In fact, Mr. Peart testified that the defendants told him that they were planning on going international with their product. (T 27).

✓ Fact No. 13 as stated in the findings is incomplete. The defendants offered to supply the Board of Health with a sample only upon the condition that the Board of Health warrant the confidentiality of the formula. Chapter 26 of Utah Code Annotated makes no provision for requiring strict confidentiality by the Board of any substances or formulas that come to the Board for inspection. There is no provision in the statute which exempts any formula or substance from meeting the requirements of the statute on the grounds that the Board will not absolutely warrant the confidentiality of the formula. However, there is a trade secret provision prohibiting the revelation of information to any unauthorized persons. Utah Code Annotated §4-26-3.12 (as amended).

Therefore, the alleged offer by the defendants was not bona fide or realistic. The defendants knew that the Board could not absolutely insure the confidentiality of the formula. Hence the actions by the defendants amounted to a refusal to offer the substance or formula to the Board. Fact fourteen as set out in the findings of fact

("The plaintiffs refused said offer") is thus true only to the extent that said offer was improperly conditional and not bona fide.

POINT II

THE FACTS 15 THROUGH 17 AS SET FORTH IN THE FINDINGS OF FACT APPROVED BY THE COURT ARE NOT GERMANE TO THE CONCLUSIONS OF LAW AND ARE NOT FACTS WHICH ARE REQUIRED TO BE MET BY THE STATE.

Utah Code Annotated §4-26-2.4(3) defines a drug in part as "articles, other than food, intended to affect the structure or any functions of the body of man or other animals." The defendants promoted the formula as a substance affecting a function of the body of man namely growing hair. Utah Code Annotated §4-26-18 does not require or provide that the State make a determination as to what the contents of a formula is. Indeed, the purpose of the §4-26-18 application provision is inter alia to permit the board to determine what the contents of the formula are. Therefore, finding of fact No. 15 is of no consequence.

Findings No. 16 and No. 17 are similarly without merit. The appellant is not required to insure the confidentiality of any formula submitted to it. The statute itself protects against the unauthorized revelation of trade secrets etc. and provides a penalty for such revela-

tion. Utah Code Annotated §4-26-3.12 (as amended 1973) and §4-26-5. The promoter of a drug can't in absence of a further provision in the statute require an additional warranty of confidentiality by the Board of Health before meeting the requirements of the Act. United States v. An Article of Drug Consisting of 30 Individually Cartoned Jars more or less,...Labeled in Part: Ahead Hair Restorer for New Hair Growth, 43 F.R.D. 181 (Delaware 1967).

POINT III

THE TRIAL COURT ERRED IN HOLDING THAT THE DEFENDANTS' FORMULA DOES NOT AFFECT OR PURPORT TO AFFECT THE STRUCTURE OR ANY FUNCTIONS OF THE BODY OF MAN.

Dr. Darrel Newell Steele, son of the defendant, and licensed only in Canada, testified that in his opinion the Melwood Steele Formula was not a drug. He defined a drug as follows:

"As a physician a drug to me means something that can be injected systemically or parenterally by needle or can be ingested, taken orally or by suppository, or can be taken occasionally topically, and that these substances have a chemical effect or a metabolic or biological effect on the body. Most drugs have a transient or cumulative effect, depending on the drug, and are metabolized by the kidneys or liver and excreted directly through the digestive system and to my knowledge most drugs would have some effect on some bodily function which would be detectable through - by chemical, anatomical, renal or urinary testing, or they would show some outward signs or effects." (T48).

He also concluded the formula not to be a drug because it "Caused no changes in Organ function in the body" (Emphasis added)(T 49).

The issue in the cases in chief is not whether the defendant's formula meets the medical definition of a drug. The issue is whether the formula in question meets the statutory definition of a drug in the State of Utah. The question is whether the formula is ". . .intended to affect the structure or any functions of the body of man. . ." Utah Code Annotated §4-26-2.5 (as amended.) (emphasis added). By the plain reading of the statute it is clear that the growing of hair is a function of the body of man. As testified to by the plaintiff's witnesses (Isaacson T-4), it is equally clear that the defendant's formula purports to affect this function.

The Utah Act is patterned after the Federal Food Drug and Cosmetic Act, §21 U.S.C.A. §321 and is the same or almost identical to the Federal Act. The Federal Courts have said that where the language of the Act is unambiguous, its words must be given their ordinary meaning. Penobscot Poultry Co. v. U. S., 244 F. 2d 94 (1st Cir. 1957). The definition of a drug in the Federal Act is intended in effect to be much broader than any strict medical definition might allow. United States v. Article of Drug...Bacto-Unidisk..., 394 U.S. 784, 89 S.Ct. 1910, 22 L.Ed.2d 726 (1969).

Also the question of whether a product is intended to affect the structure of the body of man so as to be a drug should be answered by considering how a particular products' claim might be understood by the ignorant, unthinking or credulous consumer. United States v. Article of Drug...47 Shipping Cartons More or less..."Helene Curtis Magic Secret..." 331 F.Supp. 912 (D.C.Md. 1971).

Clearly the growing of hair is a function of the body of man regardless of the medical definition of such function. Both the plaintiff's doctor and the defendant's doctor testified that growing hair is a function of the body of man. (T-4, 54).

POINT IV

THE EVIDENCE CLEARLY SHOWS THAT THE MELWOOD STEELE FORMULA IS A DRUG, AND THE FACT THAT THE FORMULA MIGHT ALSO BE A FOOD OR A COSMETIC DOES NOT PRECLUDE IT FROM BEING A DRUG. THEREFORE, THE TRIAL COURT ERRED AS A MATTER OF LAW IN DETERMINING SAID FORMULA WAS NOT A DRUG.

Under the Federal Act the intended use of an article is the primary factor in determining whether it is a drug within the meaning of the Act, regardless of its inherent

properties or dictionary definitions. United States v. Articles Consisting of 36 Boxes, More or less, labeled "Line Away, Temporary Wrinkle Smoother, Coty" 284 F.Supp. 107 (D.C.Del. 1968), affirmed 415 F.2d 369 (3rd Cir 1969) United States v. 3 Cartons, More or Less, "No. 26 Formula GM etc." 132 F.Supp. 569 (S.D.Cal. 1952). Even if the defendant's unsubstantiated claims are true that the formula is made up solely of food products which may be purchased in a grocery that does not mean the formula is not a drug. If the formula itself is a food it would not be precluded from being a drug. Honey has been held to be a drug, when it is labeled or promoted as having properties which come within the definition of a drug as set forth in the Federal Food, Drug and Cosmetic Act. 21 U.S.C.A. §321. United States v. 250 Jars, etc., of U.S. Fancy Pure Honey, 218 F.Supp. 208 (E.D.Michigan 1963), affirmed 344 F.2d 641.

Also under the Federal Food Drug and Cosmetic Act the fact that an article is a cosmetic does not preclude it from being a drug. United States v. Article Consisting of 216 Cartoned Bottles, More or Less, Sudden Change, 288 F.Supp. 29 (D.C.N.Y. 1968), reversed on other grounds 409 F.2d 734; United States v. Articles Consisting of 36 Boxes, etc., Supra.

As already pointed out the key factor in determining whether a product is a drug is its promotion. If the labeling or promotion attributes characteristics to a

product that would bring it within the act's definition, it will be deemed a drug Kordel v. United States, 335 U.S. 345, 69 S.Ct. 100, 93 L.Ed 52 (1948); United States v. Hohensee 243 F.2d 367 (3rd Cir. 1957), cert.den. 353 U.S. 976, 77 S.Ct. 1058, 1 L.Ed 2d 1136.

The Melwood Steele Formula has always been promoted as a drug which purports to affect the function of growing hair.

CONCLUSION

The defendants were promoting their formula as a drug without meeting the requirement of the Utah Food Drug and Cosmetic Act. Therefore, the decision of the trial court should be reversed.

Respectfully submitted,

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Dated, November 12th, 1976