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Food Drug Cosmetic Law JOURNAL

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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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The Real Food and Drug Law

By DONALD L. METZGER

Mr. Metzger, Who Is a Student at Northwestern University School of Law, Prepared His Paper for a Seminar on Food and Drug Law, Under the Supervision of George M. Burditt and Merrill S. Thompson, Instructors in Food and Drug Law and Members of the Illinois Bar.

AN INQUIRY into what, in a general sense, constitutes the law in a particular subject matter or area will naturally lead one along several separate paths of examination. In the interest of making full academic discovery, he should follow them all; in the interest of achieving meaningful explanations of what is discovered, he should connect them all. Such is the artificial construction one must impose upon what may seemingly be a disjointed conglomeration of fact and opinion. This is done of necessity, for the end of any investigation is to relate that which is found to that which is sought.

This task can at once be simplified by establishing the meaning of certain concepts fundamental to the inquiry in terms of their limited purpose in the inquiry. Law, then, should be understood herein in two senses. The first refers to politically legitimate, or authoritative, rules of conduct. The second refers to what may be thought of as the legal process, the authoritative regulation of conduct by the application of the established rule.

The idea of authority in the concept of law is especially significant in the context in which law is here under consideration. For it will be seen that, in the regulation of conduct, the law is dependent upon the

interaction of two factors: the degree of voluntary compliance, and the probability of enforcement. If law may be considered effective to the extent that its regulation of conduct is due to the greater magnitude of the former, and the lesser need of the latter, then it should be clear that the recognition of the authority which forms the foundation of the law is directly related to its effectiveness, in that such a legitimization of authority will increase the likelihood of voluntary compliance. Other factors relating to compliance are not here material.

The authority which underlies the law is the source of the law. In the area of regulation of the food and drug industries, as in the area of any segment of the economy for which there exist an administrative regulatory agency, the source of the law is at once legislative, executive, and judicial. But it is the particular interrelationship of these general sources, and the manner in which they function, that shapes this area of the law.

In determining what is the law which governs the regulated industries in the food and drug sector, one must focus attention, as in most instances of federal legislative delegations, primarily upon the regulatory agency, and upon the attitude of the courts towards the performance by the agency of its statutory duties. In substance, it must be determined where and by what processes the rules of conduct are made by which the activities of the industries are regulated. To the extent that agency determinations are accepted as binding by industry, and, in addition, to the degree to which the courts refuse to substitute their judgment for that of the agency, the law is, in fact, what the agency is willing to decide is the law, however this decision may be reached. That this is the case will be seen in the specific context of the administration of the Food, Drug, and Cosmetic Act.

In general, the Act is an enabling statute which, with its several amendments over the years, is a broad delegation of authority to the Food and Drug Administration (FDA) to administer the Act. The statutory scheme consists of basic provisions which, with specific modifications in many instances, are self-executing, substantive rules of conduct. There is little or no discretion committed to the agency with regard to the administration of these provisions. The law here is the statute, as enacted by Congress, and the interpretation placed upon it by the courts in applying it to particular fact situations. In addition, however, are the provisions of the Act which, taken as a

whole, constitute a delegation of substantial authority to FDA. Agency activity in these areas is thought to benefit from the expertise, continuity, specialization, and sympathetic administering which Congress felt the agency could bring to bear. The limits of permissible administrative action will be seen to be dependent upon these powers delegated to the agency by Congress, as used in a specific regulatory context.

Authoritative Effect

Under the Act, the FDA can issue guidelines, interpretative rules, and substantive regulations which have the force and effect of law. No limitations are imposed by the Act upon the procedures to be used in the issuance of guidelines or interpretative rules. General provision for such actions will be applicable to particular sections of the statute; in these areas the problem of procedural safeguards must be considered in terms of Congressional intent, the Administrative Procedure Act, and the judicial review held by the courts to be appropriate. The Act, however, is quite explicit with regard to the procedures which are to be followed in the issuance of substantive regulations. And it is in this regard that the scope of judicial review is determinative of what is the source of the law, or, in other words, of when certain agency regulations have the force and effect of law.

Varying degrees of authoritative effect, upon review or enforcement of such regulations, are accorded to those regulations by the courts. One may conceive of a spectrum of authoritative effect, at one end of which will be regulations which the courts will treat as tantamount to Congressional legislation. They must have been enacted with the statutory procedural requirements, and of course may not be arbitrary or abusive of agency discretion. As regards regulations at the other end of the spectrum, the court will substitute its own judgment on the matter; it will, in effect, determine the matter *de novo*. While analysis is easier within the context of specific compliance or enforcement aspects of a particular agency action pursuant to a specific statutory provision, it is nonetheless meaningful in a more generalized sense.

It should, of course, be understood that not all agency regulations can easily be classified as to their authoritative effect; not all regulations will fall at one end of the spectrum or the other. The concept of authoritative effect of a regulation should be understood, as suggested

above, in terms of the quantum of judicial review which the courts will afford on the merits of agency action which purports to define standards of conduct for the regulated industries.

It cannot seriously be contended that an agency like the Food and Drug Administration will tend to consider the legitimacy of its actions paramount in importance to the achievement of positive solutions to problems. Hence, one must turn to the courts for the ultimate protection against administrative abuse. Though not every agency action should be closely supervised, there will be instances when judicial review is critical. So the courts themselves must have at least a fairly well-defined notion of the authoritative effect of regulations.

The term legislative regulation may be applied where the statute fails to create a substantive rule of conduct, but seems to provide that failure to comply with the agency regulation will constitute a violation of the statute. The term interpretative rule may be applied where the statute does in fact create a substantive rule, but where the command of the statute is more or less general, so that the agency may enact a regulation by which it attempts to interpret and define the general statutory language. To the extent that they may define standards of conduct, both the legislative and the interpretative rules may be substantive.[1]

The significance of this classification for the effect on the scope of judicial review should not be underestimated. It was discussed, in fact, by the Attorney General's Committee on Administrative Procedure in 1941.

> Administrative rule-making, in any event, includes the formulation of both legally binding regulations and interpretative regulations. The former receives statutory force upon going into effect. The latter do not receive statutory force and their validity is subject to challenge in any court proceeding in which their application may be in question. The statutes themselves and not the regulations remain in theory the sole criterion of what the law authorizes or compels and what it forbids. . . . This distinction between statutory regulations and interpretative regulations is, however, blurred by the fact that the courts pay great deference to the interpretative regulations of administrative agencies, especially where these have been followed for a long time. . . .[2]

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[1] William F. Cody, 21 *Administrative Law Review* 347, and Davis, *Administrative Law Treatise*, Section 5. The preceding four paragraphs present the substance of Mr. Cody's excellent discussion of the administrative process, which is highly relevant to the food and drug area, and which, along with Professor Davis' concept of authority, supports my approach as stated at the outset.

[2] Report of the Attorney General's Committee on Administrative Procedure, in Cody, footnote 1, above. The following four paragraphs contain more of Mr. Cody's discussion.

Thus, when speaking of the force of law as applied to administrative regulations, as determined by their authoritative effect upon judicial review, what is meant is that certain regulations, the legislative regulations, will be subject to only a minimum of judicial review, as required by the Constitution and the Administrative Procedure Act. And the distinction, as felt in the context of the scope of judicial review, between legislative and interpretative regulations should be understood to depend upon, and be a manifestation of, the legislative intent as expressed in the Food, Drug, and Cosmetic Act. It is certainly well settled that Congress may delegate to an agency, as it has in this act, the power to legislate substantive standards not specified in the Act. It is in these instances, involving explicit statutory delegation, that the courts have been willing to find legitimate agency power to promulgate legislative regulations, and have, as pointed out before, restricted the scope of review to an inquiry as to whether the particular regulation was promulgated in accordance with the procedures prescribed by the statute, and whether it is arbitrary or unreasonable in the context of the statute.

It must be realized that the authoritative effect of an FDA regulation is not in fact litigated if judicial review does not occur either directly or in an enforcement action; FDA can hardly be thought capable of ruling, with any binding effect, upon its own jurisdiction and powers. But members of the regulated industries, as well as the agency, will want to know whether the court will apply a regulation as a definitive and binding criterion for determining violations of the Act, or will treat it as constructional opinion only, for which it may substitute its own judgment as to whether particular conduct is a violation of the law.

Classification of Regulations

The classification of agency regulations as legislative or interpretative, on the basis discussed above, can help in making this determination. It must be asked whether the regulation is clear as to the effect it purports to have. It should be ascertained under which sections and provisions of the statute the regulation is promulgated. This will indicate the purpose and the statutory basis of the rule. The value of such an inquiry will immediately become apparent when made within the specific framework of the Act.

Several provisions of the statute refer to the agency's procedure in enacting regulations. Sections 701 (e) and (f) contain explicit requirements for the issuance of regulations which implement certain named statutory provisions. A few other substantive statutory provisions contain their own rule-making procedures or incorporate 701 (e) procedures. All other rule-making procedures are carried out under section 701 (a), a sort of general rule-making provision. Nowhere in any of these provisions is there an express statement concerning the authoritative effect the regulations are to have. However, there is the implication in the phrase "substantial evidence of record" in section 701 (e) that a reviewing court may not substitute its own discretion for that of the agency. And the House Committee Report accompanying the bill that was to become the Food, Drug, and Cosmetic Act, in 1938, classified regulations under section 701 (e) as legislative for purposes of authoritative effect. "Such regulations are not merely interpretive. They have the force and effect of law and must be observed."[3] Furthermore, the specific statutory provisions referred to in section 701 (e) are not self-executing and do not state substantive rules of conduct. Section 701 (a), on the other hand, conferred power to enact only what the Congress referred to as "merely interpretive" regulations.

It is clear that legislative rule-making authority involves a greater delegation of power by Congress. Where this is the case, the statutory provisions do not establish standards of conduct; the agency has been given the ultimate power to determine the content of the law, and the concomitant scope of judicial review is naturally quite narrow, as the legislative body has placed the power in the agency, and not in the courts. Here, the agency action is the law. Interpretative regulations should not be deemed to be binding upon a court in a specific enforcement action. The law is embodied in the statute, to a greater or lesser degree, and the court is free to interpret the statute, and to substitute its own judgment for that of the agency. Only to the extent that the court refrains from exercising its power can an interpretative rule have the force and effect of law. As Professor Davis suggests, interpretative regulations may be accorded varying degrees of authoritative effect by reviewing courts, from virtually binding effect, at one extreme, through a highly persuasive effect, to a merely guidance or advisory effect which the court may choose to overlook if it wishes, at the other end of the spectrum.[4] The courts should, and

[3] House Report No. 2139, 75th Congress, 3d Session (1938).

[4] Davis, footnote 1, above.

generally do, make allowance for a full hearing by the court, in an enforcement action, regarding the validity of an interpretative regulation as applied to the particular factual context.

Rule-Making Functions

This theoretical or jurisprudential basis for determining the authoritative effect of formal FDA action is of only limited applicability to the actual conduct of the administering of the Food, Drug, and Cosmetic Act. The rule-making functions of the agency are extensive and complicated; they comprehend numerous provisions of the Act, concerned with several matters of regulation, such as the establishment of standards of safety, identity, labeling, and packaging; the establishment of exemptions and tolerances, and the establishment of procedural and organizational rules. Actual agency procedure is almost as varied as the areas of regulation. And while rather explicitly prescribed and fairly executed in matters of legislative rule-making of broad scope, it seems to break down in the numerous areas where the work load has been made heavy by additional grants of substantive authority by the Congress. A substantial amount of rule-making in the Administration has, in fact, no specific procedures set forth in the Act. The courts have generally held that interpretative rulings require no hearing, evidence, or findings, for, as pointed out above, the interpretation given is merely the agency's understanding of the law, and can be reviewed in court when an actual, and ripe, controversy arises. And Section 4 of the Administrative Procedure Act, defining the rule-making responsibilities of agencies generally, is certainly applicable. But the agency does not always comply with these requirements, and resort to the courts is not often made.

Officials of the FDA have mistakenly suggested that rule-making in the agency is not the making of law, but the administration of law. They point out that rules promulgated are within the framework and the avowed purpose expressed and implicit in the act of Congress, and characterize their activity as interpretative and implementary within the boundaries set by the legislative body. Besides broad authority to prescribe general procedural and definitive regulations, there is authority to establish rules to explain what is required by particular provisions of the Act, and to describe the activities and the conduct that

will be considered violative—by the agency. Its function is to tailor the law to fit specialized situations; it must be solidly grounded in all of the relevant and pertinent facts.[5] In many areas, the fundamentals of rule-making, it is felt, consist of precise, controlled, scientific testing, and evaluation of the results. Such judgments must be made essentially by experts. Laymen are bound to accept their fair evaluations and judgment decisions. It is not to be suggested, of course, that the right to a hearing, with counsel and cross-examination of the experts, should be dispensed with, whenever there is a real controversy, and fairness entitles the parties affected to judicial review. The regulations promulgated are not immutable but can be changed whenever convincing evidence is available to persuade the Administration that a change is needed.

The law which is administered by the FDA has, through Congressional amendment of the Act and the expansion of the activities of the agency, kept abreast of changing technology. This has necessitated, correspondingly, a certain evolution in the law and its administration, as the statute dealt more and more with affirmative requirements.[6] The trend has been strongly in the direction of requiring prior approval before marketing products, and the basic philosophy of the FDA, and the thrust of its activities, have been to employ preventive measures rather than punitive enforcement. Emphasis has been placed upon government preclearance, pretesting, and pre-approval. Congress seems to be relying to a greater extent than before upon the agency to interpret the statute and pinpoint the activities that will be and will not be tolerated.[7] This trend away from the philosophy of a regulatory statute which separates judicial and legislative powers, and which establishes objective standards of conduct which may be tested in the courts, to the philosophy of regulation by license or administrative expertise has increased the administrative authority of the FDA, and has had a substantial impact upon the authoritative effect of agency actions in general.

Increased Consumer Protection

Administrators have been finding it possible to increase the consumer protection available under the Food, Drug, and Cosmetic Act.

[5] John L. Harvey, 13 Food Drug Cosmetic Law Journal 685.

[6] George P. Larrick, 18 Food Drug Cosmetic Law Journal 133.

[7] Franklin D. Clark, 16 Food Drug Cosmetic Law Journal 500.

The authority of the agency should be exercised to produce and maintain a balance between public and private interests. The characteristics of agency administration of the law—adaptability, specificity of rule-making, capacity for adjustment to change—should enable it to strike suitable balances among the interests served by the agency. The history of food and drug legislation and administration reveals a long story of co-operation among the branches of government and the regulated industries. Enforcement legislation has progressed and must be adapted to the advancement in the techniques of the industries which it regulates. But the sympathetic, helpful friend of industry—the FDA—is also its policeman. The problem is to find the point of maximum justice to both producer and consumer. The concept of public trust has not gone unrecognized by industry; to the extent that it guides counsel and their clients in this field, it helps secure the orderly operation and progress of the law. It is the underlying concept implicit in many legal questions; it may be considered analogous to the rule of consumer expectation applied by the courts in certain types of cases. But public trust is likewise the province of FDA, which must be responsive to public opinion to keep the food and drug laws up with developments in history. FDA feels the public expects it to act as a third-party arbiter, to respond to new technology so that it serves the interest of the consumer as well as that of the producer.

The nature of the functions of the FDA, as a balancer of interests, the breadth of the delegations of authority made to it by Congress, and its philosophy of preventive enforcement have combined to shape the processes which determine the law in fact in the food and drug area. To be sure, FDA has established rules which outline what those concerned may submit as a basis for making decisions. Submissions are supplemented by discussions with members of industry. The purpose of regulations, once established, for the enforcement of the statute, is to communicate to the regulated industries what the agency thinks is expected of them. It is hoped that, in the communication in such specific terms as to avoid misunderstandings and inadvertent violations, voluntary compliance can be achieved by regulations. Regulations expected to be binding are published, annually revised, and possibly changed from day to day. Furthermore, all statements of general policy and interpretation, once informal advice offered as Trade Correspondence, are formalized to the extent needed for publication. Congress has seemingly been impressed that rule-making

can be more effective than case-by-case adjudication in implementing its policy as contained in the Food, Drug, and Cosmetic Act. Yet, as will be shown, such activities, in conjunction with the formal rule-making considered earlier as to its authoritative effect, accounts for only a fraction of what is probably viewed as the law by the industries under regulation.

Questions of the inauguration of legal actions where significant violations are encountered must be determined, for the agency is unable to give equal attention to all of the products subject to the laws which it enforces. The work of the field district laboratories must be programmed to give attention to those categories which FDA decides are of the greatest importance to the consumer. The FDA does not believe that the existence of the law or the enforcement activities alone could result in the breadth and depth of consumer protection which should be afforded.[8] Rather, as suggested above, the agency is committed to the view that a great degree of voluntary compliance should be encouraged. Major controls are exerted through the administrative processes of new drug, pesticide, food additive, and color additive preclearance and surveillance. The fact that in the 1940's approximately 3,000 enforcement cases were brought per year, whereas now, despite the huge growth in the regulated industries and in the authority of FDA, only about 1,000 are brought,[9] would seem to accent the emphasis placed by the FDA on voluntary compliance rather than enforcement, and its success.

Voluntary Compliance

This success is due in no small measure to what might be considered as the great body of unwritten law which seems authoritatively to regulate the conduct of the food and drug industries. This is the result of what is called informal agency action. It is the product of several interrelated factors, such as the kinds of problems which the FDA faces, the nature of the agency-industry relationship, the attitudes of the courts toward the activities of FDA, and the nature of food and drug litigation. It thrives in the environment described above.

> Regardless of legal provisions governing administrative procedure and judicial review, the environment of decision making gives the agency virtually complete discretion . . . (M)ost decisions are made at an informal level. Because of the dominant position of the informal decision making process very few cases, relatively speaking, reach the courts. Individuals and groups use the informal

[8] William W. Goodrich, 20 FOOD DRUG COSMETIC LAW JOURNAL 197.

[9] Goodrich, 22 FOOD DRUG COSMETIC LAW JOURNAL 234.

process because it is less time-consuming and expensive, and does not result in straining relations with the agency too much. Further, very little publicity is given to informal proceedings; therefore, many business interests that consider good will an important asset prefer this form . . . because the public need never know they have been involved in illegal or questionable activity of any kind. The same factors that keep private parties away from the formal hearing process result in limiting judicial review. The courts are available, but all too frequently taking a case to them is self-defeating. Moreover, the courts themselves have adopted doctrines of review that give the agencies maximum discretion.[10]

In the informal stage of the administrative process, decisions are made on the basis of informal correspondence, interviews, conferences, and inspections, rather than on the basis of formal hearings. The second, or formal stage, becomes operative only when the first stage has not been dispositive of the problem, and even within the formal agency processes informal procedure is extensively utilized. By far the greater number of matters which come before the agency are settled informally, and with authoritative effect.

The FDA seeks to bring about consumer protection without constant resort to litigation. It attempts to find new ways of accomplishing its statutory purposes with a minimum of friction and disruption and a maximum of public protection, and industry co-operation. The agency feels that the public good will be better served through prompt and direct administrative action rather than through the long processes of hearings and litigation, where the statistics fairly conclusively demonstrate that the government almost invariably wins. As Commissioner Goddard explained:

We are not calculatingly unreasonable. We do not issue any edicts without foundation. We do not take any summary action. We do not inflict undeserved penalties. We do not hold Star Chamber proceedings. . . . I prefer by far to carry out this responsibility with the active help and cooperation of the companies that produce our foods, our drugs, and our cosmetics. I prefer to do it by creative administration. It is only as a last resort that we go to court. But we have been in court before, and we shall be there again.[11]

In fiscal 1967, about 1500 civil and criminal cases were referred to the Department of Justice. Of those going to trial, the government lost six.[12]

The need for informality, private conferences, and speed is of course clear. Apparently, many members of the bar and industrial representatives prefer the *ad hoc* procedures currently in vogue at the FDA in those areas where specific procedures are not provided. When the results are unsatisfactory to the informal participants, or when the

[10] Peter Woll, *American Bureaucracy*, p. 64.

[11] Dr. James L. Goddard, 22 Food Drug Cosmetic Law Journal 449 (454).

[12] See footnote 11, above.

FDA acts in an arbitrary fashion, there is no relief where there is no established procedure. There are, to be sure, situations in which hearings can be held, limited to the matters in controversy.

The increasing complexity of the agency's functions, and the continuing shift of responsibility to securing prior approval have also contributed significantly to the predisposition of manufacturers and producers who deal with the agency to comply with FDA demands rather than participate in lengthy, expensive litigation, likely to damage the good will of the company. And the problems of procedure raised by the change in the thrust of administrative activities from the techniques of policing—seizure, injunction, criminal prosecution—to licensing-type activities requiring prior approval have strengthened agency authority. This is so because the procedure contemplated under the Act utilizes rule-making methods rather than those of adjudication; but the emphasis on prior approval makes the rule-making almost indistinguishable from what should be adjudicatory hearings. Thus it might be urged that informal adjudication characterizes much agency action. Furthermore, the burden of proof is shifted to the industry to justify in advance its right to manufacture or market a particular product. The government need no longer go into court; the manufacturer must demonstrate the safety and efficacy of his product, and the validity of his claims. And the agency, reluctant to sacrifice its discretion to more formalized processes, conducts its activities in an environment of informality in which it is dominant.

Open Door Policy

The recognition by the FDA of the advantages inherent in informally reaching agreements on facts and rules is embodied in what it considers its open door policy. Anyone not frivolous can go to the agency about any matter with which he is concerned, and receive respectful attention, comment, and reply without formalities or procedure. The Division of Advisory Opinions in the Bureau of Enforcement offers free consultation and advice by mail, telephone, or in person on compliance matters for any firm or individual requesting it. This advice assists those seeking to comply voluntarily with the law.[13]

New compliance approaches are utilized to reinforce reliance on enforcement through inspection and laboratory staffs. Co-ordinated government-industry efforts, under the aegis of the Bureau of Voluntary

[13] John L. Harvey, 13 Food Drug Cosmetic Law Journal 685.

Compliance, have supplanted traditional law enforcement by means of district industry workshops, quality assurance programs within firms, trade association central laboratory testing programs, and improved communications and information dissemination.[14]

Professor Davis terms this administrative reliance on informal enforcement methods the use of the agency's "supervising power." In place of formal adjudication is the lifted eyebrow—the suggestion or implied threat of action or publicity. This mode of administrative enforcement constitutes the bulk of agency regulatory action, and law-making. "The court cases bear about the same relation to total agency conduct," rails H. Thomas Austern, "as the visible portion of an iceberg does to what lies beneath the surface of the sea."

> In practical terms, the Code of Federal Regulations is as current and reliable as the old English Pipe Rolls . . . (I)n this field what the agency concludes, the court approves; and most of those regulated do not often dare to challenge an informal assertion of power. . . . Never forget that where the FDA disagrees, the product is outlawed. . . . In many FDA situations, it may be wholly beyond the power of an individual to know or to control whether or not he is in compliance. . . . There is, of course, in these statutes detailed provisions for court review. . . . But every experienced food and drug lawyer will tell you that in 999 out of 1000 cases, even the most sanguine counsel knows that he hasn't a prayer of persuading an appellate court to second-guess FDA. . . . The FDA rule-making process, by and large, has virtual immunity from judicial intervention or correction.[15]

It should be realized that this practically unreviewable, intricate rule-making authority, and interpretation of its own regulations, is backed up with the sanction of strict criminal liability. This is not to imply that the FDA makes indiscriminate application of this sanction; it is merely to add to the description of the environment within which much informal agency action takes place.

Vincent A. Kleinfeld has embellished upon this description:

> (I)t seems to be inherent in all government agencies to strive ceaselessly to expand their authority. . . . The tremendous desire of the courts, from the Supreme Court down, has been to convert this compromise statute into an extremely strong law. . . . The generalization that the Federal Food, Drug, and Cosmetic Act must be construed liberally is virtually a substantive rule. . . . Practically any construction of the Act by the government which would strengthen the consumer protection offered by it would be upheld.
>
> (I)mportant positions are taken by the Food and Drug Administration in 'Statements of General Policy or Determination,' again without a hearing, and sometimes even more informally by a press release. These may be changed from time to time, so that which the Food and Drug Administration would consider not to be a criminal offense at one time, may turn into an offense at another.

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[14] Fred J. Delmore, 23 FOOD DRUG COSMETIC LAW JOURNAL 227.

[15] H. Thomas Austern, 18 FOOD DRUG COSMETIC LAW JOURNAL 617 (617-631).

The Food and Drug Administration is by far one of the better and more competent federal agencies and is less influenced by political considerations than most other agencies. Its approach, however, is sometimes what can be called the 'end-justifies-the-means' approach. (A)ny approach which the courts may possibly accept is justified. . . . Perhaps because rule-making hearings under the (Act) are time consuming and costly, and probably because in most instances the government has made up its mind anyway as to the final regulation which will be issued, there is a growing reluctance to grant hearings at all. . . .

The specialist in the food and drug area, however, although he may have concluded that his client's position is legally correct, must now try to speculate whether the government will differ and whether the courts, by some miracle, will take issue with the government's position.[16]

Scope of FDA's Authority

The administrative processes in the food and drug area present a striking example of the ability of a regulatory agency like FDA to influence the conduct of those it regulates without resort to the courts. With regard to the formal regulations which the agency issues, the courts, on the basis of the apparent intent of the Congress as expressed in the Act, have determined the authoritative effect to be accorded agency actions by carefully circumscribing the scope of judicial review. In many areas, the statute, as construed by the courts where it is felt this is appropriate, is the law which confronts the regulated food and drug industries. In other areas, where Congress has made a broad delegation of legislative powers, the agency itself makes the substantive law. In still other areas, where the Congressional delegation is more narrowly limited, the actions of the agency are not, strictly speaking, the law, for the courts may always substitute their judgment as to what the statute commands. In these areas, the general pattern of court decisions is indicative of the authoritative effect that may be attributed to agency determinations. The bulk of FDA action which serves to regulate the conduct of industry, however, is probably not contained in the formal enactments of the agency. Rather, it consists of informal activity manifested in various ways, all of which is not reviewable by the courts. But the disposition of the courts to uphold agency interpretations, the great expense of litigation, the need for speedy resolution, the damaging effect of publicity, and the threat of criminal sanctions, create an environment in which voluntary compliance is difficult to resist, and give to much informal agency action the authoritative effect of law.

[The End]

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[16] Vincent A. Kleinfeld, 17 FOOD DRUG COSMETIC LAW JOURNAL 404 (404-417).

The Effect of NAS-NRC Review on Me-Too and Post-'62 Drugs

By HUGH A. D'ANDRADE

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THE ORIGINAL CONTRACT BETWEEN THE FDA and the National Academy of Sciences-National Research Council (NAS-NRC) providing for the review of the efficacy of drugs given New Drug Applications (NDAs) between 1938, and October 10, 1962,[1] was signed nearly four years ago.[2] That review has now been completed, and we are in the midst of the problems which its implementation creates for the holders of the new-drug applications of the products reviewed. As yet, however, there has been little experience with the problems which efficacy review will create for products which were not directly reviewed.

Post-'62 Drugs

The first group of non-reviewed drugs is made up of those whose NDAs were approved after October 10, 1962. Since these drugs were found, at least theoretically, not to lack substantial evidence of effectiveness, they were not reviewed by the NAS-NRC. They may, however, be affected by an NAS-NRC review of a pre-'62 drug. An example is the thiazide-potassium chloride combinations. On September 5, 1969, a Drug Efficacy Study Implementation was published for certain of those drugs.[3] The products there listed were those

[1] The effective date of the Kefauver-Harris Amendments, Public Law 87-781, 76 Stat. 789 and following.

[2] April 29, 1966.

[3] 34 C. F. R. 14089.

which had been NDA'd prior to October 10, 1962. The notice stated that: "Other new-drug applications approved for fixed combinations of a thiazide with potassium chloride shall be similarly affected."[4] When the Notice of Opportunity for Hearing on Proposal to Withdraw Approval of New-Drug Applications for these combination products was published on February 7, 1970,[5] it included, in addition to the pre-'62 drugs, one approved subsequent to October 10, 1962. Does the holder of that post-'62 NDA have any rights unavailable to those with pre-'62 NDAs?

The FDA in its proposed amendments to 21 C. F. R. 130.14[6] states that no hearing will be granted prior to withdrawal of approval of an NDA where the applicant cannot identify adequate and well-controlled clinical investigations to support the claims of effectiveness. Since presumably the post-'62 application was approved on the basis of such investigations,[7] the FDA should find it difficult to deny a hearing to the holder of that post-'62 application on this basis.

Another distinction is in the burden of proof. Informally, the FDA has taken the position that in Section 507 revocation proceedings, the burden of proof is on the manufacturer. As to 505(e) withdrawal proceedings, the FDA's proposed amendment to 21 C. F. R. 130.14 is only consistent with a view that the burden of proof is on the applicant. It has been held, however, that where an application had become "effective" (the case arose prior to the '62 amendments), the FDA in a withdrawal proceeding has the burden of proving that the drug is "unsafe."[8] It would appear, therefore, that in the case of a post-'62 approved drug the FDA bears the burden of proof. Since the statute[9] requires the factual finding of the Secretary to be given conclusive effect on appeal if supported by substantial evidence in the record, I take it that this burden is that of producing substantial evidence of a lack of substantial evidence of effectiveness.

Me-Too Drugs

The other group of drugs which were not reviewed are those which were first marketed subsequent to passage of the 1938 Act[10]

[4] 34 C. F. R. at 14090.

[5] 35 C. F. R. 2734.

[6] 35 C. F. R. 3073-3074, February 17, 1970.

[7] See Sections 505(c)(1) and 505(d)-(5) (21 U. S. C. 355).

[8] *Bell v. Goddard*, (CA-7 1966) 366 F. 2d 177, 181.

[9] Section 505(h), (21 U. S. C. 355(h)).

[10] Drugs marketed prior to June 25, 1938, the effective date of the 1938 amendments, were exempted by the terms of Section 201 (p) (21 U. S. C. 321(p)) from being considered "new drugs." This exemption was continued in the '62 amendments.

and prior to October 9, 1962, and never NDA'd. To understand how NAS-NRC review might affect these drugs, some discussion of the "grandfather" clause is necessary.

Section 107(c)(4) of the '62 amendments exempted from the amended definition of "new drug"[11] marketed drugs which on October 9, 1962, were generally recognized as safe and were "not covered by an effective application."[12] Henceforth I shall refer to "107(c)(4)" rather than the "grandfather" clause to distinguish this provision of the '62 amendments from the "grandfather" clause in the 1938 Act, which is found in the body of 201(p) itself and totally exempts drugs in the market prior to June 25, 1938, from being considered new drugs.

As early as 1963,[13] the FDA took the position that 107(c)(4) exempted from the requirements of efficacy only those drugs which never had any clearance through the new-drug procedures. The counter-position is that 107(c)(4) protects any drug which was generally recognized as safe on October 9, 1962, whether or not previously NDA'd. As I understand it, the theory of this position is that a drug which was generally recognized as safe on that date was "not covered by an effective application." It is rather as if the NDA were like a tadpole's tail which fell off and was gone forever when the drug became generally recognized as safe. The principal problem I see in this position is that if "not covered by an effective application" requires only that that the drug have been generally recognized as safe, its addition to the requirement of 107(c)(4)(B) that the drug not have been a new drug on October 9, 1962, was unnecessary.

Another weakness is posed by the following hypothesis. Suppose a drug had been NDA'd in the early 1950's and thereafter became generally recognized as safe. If an unforeseen problem of toxicity had

[11] Section 201(p) (21 U. S. C. 321 (p)) was amended by adding lack of general recognition of effectiveness to the definition of "new drug."

[12] In full, 107(c)(4) reads as follows: "In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201 (p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of the Act, the amendments to section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."

[13] February 15, 1963, FDA conference on the Kefauver-Harris Drug Amendments.

then developed which deprived the drug of general recognition of safety, could the manufacturer have been prosecuted for marketing a new drug without an effective NDA? I think not.

Misbranded Me-Too Drugs

Being all that as it may, however, let us consider the problems NAS-NRC review creates for those drugs first marketed between June 25, 1938, and October 9, 1962, which were never the subject of an NDA.

Take the case of a drug which is a me-too of an NDA'd drug which loses one or more of its indications as a result of NAS-NRC review. If the never NDA'd me-too drug has not changed its labeling since October 9, 1962, can it not rely on its "not covered by" protection and remain on the market under that labeling?

The first area of inquiry is whether 107(c)(4) protects such a drug from a charge of misbranding under Section 301(a).[14] *Allan Drug*[15] teaches that it does not. The genesis of Allan Drug's problem was a seizure and subsequent condemnation on the basis of false claims of efficacy for a drug which, from all indications, was entitled to the protection of 107(c)(4). Rather than argue that the misbranding charge was contrary to the intent of 107(c)(4), Allan Drug contended that changes in labeling required as a result of a misbranding attack should not deprive a drug of its 107(c)(4) exemption from the clearance provisions of Section 505. I would suspect that Allan Drug thought the Court would be unsympathetic to an argument which would have permitted the continued use of false claims. I think the Allan Drug attorneys were right. In my opinion, 107(c)(4) was not intended to permit the marketing of drugs for uses for which they are ineffective; it merely protects certain drugs as to which the FDA cannot prove *ineffectiveness* from the burden of *affirmatively* proving their effectiveness by the 505 approval route.

If this is so, should not the FDA be satisfied with its power through the use of 502(a) to prevent the marketing of ineffective drugs? I think that the FDA is not satisfied, primarily because the

[14] 21 U. S. C. 331(a).

[15] *U. S. v. Allan Drug*, 357 F. 2d 713 (10th Cir. 1966) cert. denied, 385 U. S. 899.

procedure requires it to carry the burden of proof on ineffectiveness. To avoid this consequence, the FDA may pursue one or more of the following courses of action.

The FDA may take the position that 107(c)(4) protects only those never NDA'd drugs which were not me-too's of NDA'd drugs. It will be recalled that 107(c)(4)(C) requires the drug not to have been "covered by an effective application" on October 9, 1962. The argument would be that the never NDA'd me-too drug was "covered by" the NDA on the pioneer drug. It is submitted that this argument is without merit. In no sense was the never NDA'd me-too drug "covered by" the NDA of the pioneer drug on October 9, 1962. Since, at least theoretically, the never NDA'd me-too drug was generally recognized as safe when it was first marketed, the existence of an effective NDA on another drug of the same chemical composition was of no significance to it. In answer, the FDA may assert that the "covered by" language must be read only in the context of 107(c)(4) and its purpose, without reference to Section 505 and its purpose. I do not know what courts will do when and if presented with this broad interpretation of "covered by," but I would hope that it would be seen as another example of the FDA attempting to stretch the statute to fit its purpose.

If the FDA fails in this frontal attack on 107(c)(4) protection, it may attempt to avoid the necessity of proving the ineffectiveness of each never NDA'd me-too drug by using the withdrawal order on the pioneer NDA'd drug as evidence of ineffectiveness. You will note that in all recent NAS-NRC implementation notices and in notices of opportunity for hearing, the FDA expressly gives notice to and invites comment and response from "any interested person who may be adversely affected by removal" of the drug from the market. As a hypothesis, suppose an NAS-NRC panel finds a drug ineffective for one of its labeled indications, and the FDA withdraws the NDA and accepts a supplement for labeling with that indication deleted.[16] On a subsequent misbranding action against a never NDA'd me-too of that drug the FDA may attempt to establish ineffectiveness by introducing into evidence the order of withdrawal as to the pioneer

[16] See Sections G. 2 of the Pyrazinamide Notice, 34 C. F. R. 5036 (3/8/69), and Sodium Succinate Notice, 35 C. F. R. 5190 (3/27/70).

drug with its implied or express finding of ineffectiveness. The FDA may claim that such an order is binding upon the me-too manufacturer who had notice and opportunity to comment and request a hearing. Such an argument raises difficult questions of res judicata and collateral estoppel, and I frankly do not know whether the FDA will prevail, but I suspect it may try.

In any event, if I were counseling the manufacturer of a never NDA'd me-too drug, I would be concerned about taking no action with regard to an NAS-NRC review implementation and relying on 107(c)(4) protection. I am not sure, however, exactly what I would advise. If I participate in the 505 proceeding, I would surely be bound. If possible, I might seek a declaratory judgment that the withdrawal of the NDA of the pioneer drug would not be binding in a subsequent enforcement proceeding against the me-too.

If the FDA does attempt to use the order of withdrawal in a misbranding action, I think the best argument that the manufacturer of the never NDA'd me-too drug can make is that, although 107(c)(4) might not protect the drug from the charge of misbranding, it does give the manufacturer the right to have the issue of effectiveness litigated in the enforcement proceeding.

Other Withdrawal Charges

Misbranding is not the only charge which the FDA might bring against a never NDA'd me-too drug following withdrawal of approval of the NDA for the pioneer drug. The FDA may argue that such a drug is an unapproved new drug because it is not generally recognized as safe. Here, keep in mind that 107(c)(4) gives exemption only from the efficacy element of 201(p). The FDA theory would be that no drug can be generally recognized as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof if that labeling includes an indication for which the drug is ineffective. If the drug has side effects, it must lose the risk/benefit ratio test used in judging safety when prescribed for a condition against which it is not effective. The FDA has, I understand, made a similar argument in the action for declaratory judgment brought by U. S. Vitamin in connection with the bioflavonoids,[17] except that there,

[17] See 33 C. F. R. 9905, July 10, 1968.

the FDA is trying to defeat 107(c)(4) protection by saying that ineffectiveness deprived the drugs of general recognition of safety on October 9, 1962. The revocation by the FDA of all the opinions which it had previously given to the effect that any article is "not a new drug" or is "no longer a new drug"[18] may have been for the purpose of facilitating this type of argument.

If faced with such an unapproved new drug charge, the manufacturer of a never NDA'd me-too drug will probably argue that the clear intent of 107(c)(4) is to protect the drug from being considered a new drug by reason of lack of efficacy, which intent should not be defeated by translating lack of efficacy into lack of safety. Such an argument, however, supposes that 107(c)(4) was intended to protect the right of drugs to be marketed for indications for which they are useless. As I have already stated, I think that 107(c)(4) was intended only to protect *effective* never NDA'd drugs from the rigors of proving that effectiveness by the 505 approval route.

Now let us suppose that the me-too manufacturer is willing to accept the judgment of the NAS-NRC panel and delete from the labeling of the never NDA'd me-too drug the indication for which the pioneer drug has been declared ineffective. When he does so, he falls victim to the rationale of *Allan Drug* and loses 107(c)(4) protection, and thus becomes subject to the efficacy requirements of 201(p). If, however, the never NDA'd me-too drug will be considered generally recognized as safe and effective by limiting its claims to those accepted by the NAS-NRC panel and the FDA, 107(c)(4) protection will not be important to the manufacturer of a never NDA'd me-too drug who is willing to accept the judgment of the NAS-NRC review panel. In this regard, it is important to note that the *Allan Drug* Court did not hold that the drug there involved *automatically* became a new drug when its labeling was changed, but only that it lost the protection of 107(c)(4). The Court said:

> This is not to say that every change in labeling must necessarily result in the manufacturer filing a new drug application to reintroduce the article into interstate commerce. It may well be that a condemned drug may be brought into compliance with the provisions of the Drug Act under the supervision of the Secretary by relabeling the article for another use for which it is generally recognized as effective. . . .[19]

[18] 33 C. F. R. 7758, May 28, 1968.

[19] *U. S. v. Allan Drug,* footnote 15 above, at 719.

Note, however, that in most, if not all, of the implementation notices published thus far, the FDA has stated that the drug is regarded as a new drug.[20] Nowhere have I seen an explanation of the rationale for this position. If the word "safe" and the word "effective" have the same meanings when used in both 505(e) and 201(p), a drug which escapes withdrawal of its NDA under 505(e) has been found to be safe and effective. As for general recognition thereof, that would seem to be provided by the conclusion of the NAS-NRC panel. The FDA may try to apply the material extent and material time requirements of 201(p)(2)[21] to support its new drug contention.[22] In my opinion, however, the application of that section is limited to those drugs which receive 505 approval and are recognized, but only to that extent, as safe and effective.[23]

I query, however, whether the FDA will make the effort to get new drug controls over never NDA'd me-too drugs which make the required labeling changes. I view the abbreviated NDA application[24] as an FDA attempt to get such control without effort, and I cannot foresee the circumstance under which I would advise the manufacturer of a never NDA'd drug to submit such an abbreviated application.

Conclusion

In conclusion, the one thing that can be stated with some certainty is that the FDA has ample means to reach the never NDA'd me-too drugs which are inferentially found ineffective in NAS-NRC panel reviews of NDA'd drugs. I am not certain, however, whether the FDA has the resources and the will to do so. **[The End]**

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[20] See 35 C. F. R. 396, January 10, 1970.

[21] 201(p)(2): "Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions."

[22] The fact that Congress thought that paragraph (2) of 201(p) was necessary indicates to me that the words "safety" and "effectiveness" do mean the same thing in both 505 and 201(p)(2).

[23] See *U. S. v. Articles of Drug Labeled in part Quick-O-Ver*, 274 F. Supp 443 (U. S. Dist. Ct. D. Md. 1967).

[24] 35 C. F. R 6574, April 24, 1970.

Recent Changes in Canadian Food and Drug Legislation

By ROSS A. CHAPMAN

Mr. Chapman Is Director-General of Food and Drugs, Department of National Health and Welfare, Ottawa, Canada. His Paper Was Presented at the 1969 Meeting of the Food, Drug and Cosmetic Division of the Corporate, Banking and Business Law Section of the American Bar Association, Held in Dallas, Texas, on August 13, 1969.

CANADIAN FOOD AND DRUG LEGISLATION was revised recently with the passage of three new bills. I will discuss the most significant points of these bills, which were given Royal Assent on June 27, 1969, and are now in force.

The three Bills are as follows:

(1) Bill S-15, an Act to amend the Food and Drugs Act and the Narcotic Control Act and to make a consequential amendment to the Criminal Code;

(2) Bill C-102, an Act to amend the Patent Act, the Trade Marks Act and the Food and Drugs Act; and

(3) Bill S-26, an Act to prohibit the advertising, sale and importation of hazardous products.

Bill S-15

As I have indicated, Bill S-15 amends the Food and Drugs Act, the Narcotic Control Act and the Criminal Code. I shall start with the amendment to the Criminal Code, since it leads to the first amendment to the Food and Drugs Act. The Criminal Code of Canada has for many years contained a prohibition on the sale or advertising of any means, instruments, medicine, drug or article intended or represented as a method of preventing conception. This prohibition, which was contained in paragraph (c) of subsection (2) of section 150 of

the Criminal Code, has seldom been used. Moreover, in recent years, this section has been strongly criticized by individuals and organizations, inasmuch as it was in conflict with current thinking on family planning. Therefore, the words "preventing conception or" were removed from this section. The definition of a device under the Food and Drugs Act has been amended to clearly indicate that it covers contraceptive devices. Drugs used for the purpose of contraception, of course, are already covered by this Act. Authority is also provided to control by regulation the advertising of contraceptive devices.

A further important amendment to the Food and Drugs Act involves the creation of a new Part IV entitled "Restricted Drugs." These restricted drugs are listed in Schedule J to the Act and at present contains the following compounds:

Schedule J

(1) Lysergic acid diethylamide (LSD) or any salt thereof.

(2) N, N-Diethyltryptamine (DET) or any salt thereof.

(3) N, N-Dimethyltryptamine (DMT) or any salt thereof.

(4) 4-Methyl-2, 5-dimethoxyamphetamine (STP (DOM)).

You will note that these compounds are all hallucinogenic drugs which have been the subject of abuse. The purpose of this amendment is to provide more effective control over these dangerous substances. Additional substances may be added to the list by the Governor in Council as the situation requires. Possession of a restricted drug, except as authorized by regulation, will be an offence under section 40(1). The penalties provided are given in subsection (2), which reads as follows:

"40.

(2) Every person who violates subsection (1) is guilty of an offence and is liable

(a) upon summary conviction for a first offence, to a fine of one thousand dollars or to imprisonment for six months or to both fine and imprisonment, and for a subsequent offence, to a fine of two thousand dollars or to imprisonment for one year or to both fine and imprisonment; or

(b) upon conviction on indictment, to a fine of five thousand dollars or to imprisonment for three years or to both fine and imprisonment."

Trafficking in a restricted drug will, of course, also be an offence under section 41 of the Act:

"41.

(1) No person shall traffic in a restricted drug or any substance represented or held out by him to be a restricted drug.

(2) No person shall have in his possession any restricted drug for the purpose of trafficking.

(3) Every person who violates subsection (1) or (2) is guilty of an offence and is liable

(a) upon summary conviction, to imprisonment for eighteen months; or

(b) upon conviction on indictment, to imprisonment for ten years."

As you are aware, it will be desirable to carry out research on a number of these drugs. Therefore, it was necessary to provide a mechanism to authorize the possession of a restricted drug for such purposes. This authority is provided in Section 44 (3) which reads, in part, as follows:

"44.

(3) . . . the Governor in Council may make regulations authorizing the possession or export of restricted drugs and prescribing the circumstances and conditions under which and the persons by whom restricted drugs may be had in possession or exported."

At this point, I should like to indicate the various levels of control provided by the Food and Drugs Act and the Narcotic Control Act. The general requirements of the Food and Drugs Act relating to such matters as labelling, manufacturing facilities and controls, apply in all cases:

(1) "Over-the-counter" drugs.

(2) Schedule F drugs.
May be sold only on prescription.

(3) Schedule G drugs (Barbiturates and Amphetamines).
May be sold only on prescription. Detailed records must be kept and submitted. Trafficking an offence.

(4) Schedule J drugs (Restricted Drugs, e.g. LSD).
May be sold or distributed only on authorization of the Minister.

Detailed records must be kept. Unauthorized possession and trafficking an offence.

(5) Narcotic Schedule.
May be sold only on prescription. Detailed records must be kept and submitted. Unauthorized possession and trafficking an offence.

(6) Schedule H drugs (Thalidomide).
Absolute prohibition of distribution or sale except for experimental purposes.

I should emphasize that the requirements for each category listed are not complete, but are intended only to show the various degrees of control available under the present legislation. Schedule J fills a gap which existed previously for drugs which are not generally used in medicine, but which are dangerous drugs either being abused or liable to abuse.

Finally, Bill S-15 provided for an amendment to the Narcotic Control Act relating to the penalties for possession of a drug listed on the Schedule of narcotic drugs. In Canada, over the past several years, we have encountered a marked increase in the number of prosecutions for possession of narcotics, particularly marihuana. As the Honourable John Munro, Minister of National Health and Welfare pointed out in moving second reading of Bill S-15 in the House of Commons on March 27, 1969:

The numbers of prosecutions for possession of a drug listed under paragraph 3 of the Schedule to the Narcotic Control Act increased between 1966 and 1968 from 493 to 1,727. But in spite of the enormous variety of individual situations involved in that number of cases, the relevant section of that act provides very little scope for flexibility, either on the part of Crown prosecutors or presiding judges or magistrates. There is no provision for the Crown to choose to proceed summarily; it is obliged to proceed by way of indictment. There is no provision for a judge or magistrate to impose a fine as the penalty; they are obliged to impose a penal sentence, though they can, of course, suspend it.

In view of this situation, the Minister proposed that Section 3 of the Narcotic Control Act be amended as follows:

"3.

(1) Except as authorized by this Act or the regulations, no person shall have a narcotic in his possession.

(2) every person who violates subsection (1) is guilty of an offence and is liable

(a) upon summary conviction for a first offence, to a fine of one thousand dollars or to imprisonment for six

months or to both fine and imprisonment, and for a subsequent offence, to a fine of two thousand dollars or to imprisonment for one year or to both fine and imprisonment; or

(b) upon conviction on indictment, to imprisonment for seven years."

This amendment will still permit the Crown to proceed by indictment and the court may, in such a case, impose a penalty to the extent of the previous maximum of seven years imprisonment. But the option will also exist under this new amendment for the Crown to proceed summarily, and in this case, the maximum penalties will be the same as those set out for possession of a restricted drug under the Food and Drugs Act.

Bill C-102

I should now like to go on to Bill C-102, an Act to amend the Patent Act, the Trade Marks Act and the Food and Drugs Act. Before going into the details of this Bill—I shall be emphasizing those aspects relating to the safety and quality of drugs—I should like to give you a little of the background of this legislation. I wish to quote from the statement made by the Honourable Ronald Basford, Minister of Consumer and Corporate Affairs, when he moved second reading of Bill C-102 in the House of Commons on October 17, 1968:

A study of the retail prices of patented drugs by three inquiries—one being an inquiry by a special committee of this house—reached the conclusion that drug prices in this country were unduly high or, at least, higher than they need be. In consequence, the government determined to do what it could at the federal level to reduce drug prices and, at the same time, maintain a situation where drug manufacturing in this country would not be unduly restrained, where pharmaceutical research in Canada would not be discouraged and where continued safety for the Canadian public would be preserved.

I believe that this paragraph states the government's position clearly and succinctly. Mr. Basford also pointed out that this legislation was only one of the steps in the government's program to reduce the price of drugs. He referred to steps which had already been taken, including the removal of the sales tax on drugs, reduction of custom duty on these products from 20 to 15 per cent, and narrowing of the application of dumping duties to drug imports.

The major thrust of the Bill related to changes in the Patent and Trade Marks Acts. It was designed to inject price competition into

the Canadian market by making it possible for firms in Canada to import drugs without fear of being subjected to infringement actions for breach of patent and trade mark rights. Under this new legislation, it will be possible for a Canadian firm to apply for a compulsory license to import a drug manufactured by a patented process. Furthermore, a person may import a drug under a trade mark registered by a Canadian company, provided the product is manufactured by a related company in some other part of the world, without infringing trade mark rights. The package of such a product must bear the name of the original manufacturer, as well as the Canadian distributor's name.

These sections proved to be very controversial, but the major criticism levelled at this legislation related to its possible effect on the safety and quality of imported drugs. Some critics suggested that the passage of this legislation would result in a flood of imported drugs of dubious quality. Since similar legislation, Bill C-190, had been before Parliament at the previous Session and had been the subject of similar criticism, the government, in drafting Bill C-102, looked very carefully at the safety aspects. The safeguards introduced to ensure, as far as possible, that imported drugs are of a satisfactory quality are as follows:

(1) **The Patent Act**

Under subsection (13) of Section 41 of the amended Act, the Commissioner of Patents, on receiving an application for a compulsory license to import a drug produced by a patented process, "shall forthwith give notice of such application or request to the Department of National Health and Welfare." This will alert the Food and Drug Directorate to the possibility of the importation of a particular drug produced by a specific manufacturer outside of Canada. During the period that the application is under study, officers of the Directorate can carry out an investigation to ensure that the drug in question meets all requirements of the Food and Drugs Act and Regulations including the manufacturing facilities and controls under which the drug was produced.

(2) **The Trade Marks Act**

It was pointed out by a number of pharmaceutical firms when the amendment to this Act was first suggested, that the formulas of

their products sold under the same trade mark in various countries, differed significantly. There was some question in the minds of officers of the Food and Drug Directorate as to whether these differences would represent any significant hazard to health. However, it was a possibility and therefore an exemption was provided in Section 49A, subsection (2). This subsection reads as follows:

"49A.

(2) subsection (1) does not apply to any use of a trade mark or a confusing trade mark by a company referred to in that subsection in association with a pharmaceutical preparation, after such time, if any, as that pharmaceutical preparation is declared by the Minister of National Health and Welfare, by notice published in the *Canada Gazette,* to be sufficiently different in its composition from the pharmaceutical preparation in association with which the trade mark is used in Canada by the owner referred to in subsection (1) as to be likely to result in a hazard to health."

(3) **The Food and Drugs Act**

Section 24 of the present Food and Drugs Act provides authority to the Governor in Council to make regulations to control the quality of all drugs sold in Canada. However, in view of the amendments to the Patent and Trade Marks Acts, it was decided to strengthen this section. Therefore, a further subsection was added to Section 24 which reads as follows:

"24.

(1a) without limiting or restricting the authority conferred by any other provisions of this Act or any Part therefor carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations governing, regulating or prohibiting

(a) the importation into Canada of any drug or class of drugs manufactured outside Canada, or

(b) the distribution or sale in Canada, or the offering, exposing or having in possession for sale in Canada, of any drug or class of drugs manufactured outside Canada,

as the Governor in Council deems necessary for the protection of the public in relation to the safety and quality of any such drug or class of drugs."

I should emphasize that I have only covered, and very briefly at that, the sections of Bill C-102 that I considered would be of greatest interest. Since this legislation only came into force on June 27, 1969, it is still too early to assess its impact either on drug prices in Canada or the Canadian pharmaceutical industry. As far as the Food and Drug Directorate is concerned, we believe that we have been given the necessary authority to adequately monitor the quality of imported drugs.

Bill S-26

And that brings me to Bill S-26, an Act to prohibit the advertising, sale and importation of hazardous products. This legislation will be administered by the Department of Consumer and Corporate Affairs. The Food and Drug Directorate, Department of National Health and Welfare will provide research and analytical services and advice on technical and medical aspects.

This Legislation provides for a Schedule of hazardous products which is divided into two parts. Products listed in Part I of the Schedule may not be advertised, sold or imported. Products listed in Part II may be advertised, sold or imported into Canada as authorized by the regulations. The actual wording of the Act relating to the Schedule as well as the penalties for violations is given in Section 3 of the Act:

"3.

(1) No person shall advertise, sell or import into Canada a hazardous product included in Part I of the Schedule.

(2) No person shall advertise, sell or import into Canada a hazardous product included in Part II of the Schedule except as authorized by the regulations.

(3) Every person who violates subsection (1) or (2) is guilty of

(a) an offence and liable on summary conviction to a fine of one thousand dollars or to imprisonment for six months or to both fine and imprisonment; or

(b) an indictable offence and liable to imprisonment for two years."

Section 8 (1) of the Act spells out in more detail the types of products which may be added to the Schedule and the basis for such additions:

"8.

(1) The Governor in Council may by order amend Part I or Part II of the Schedule by adding thereto:

(a) any product or substance that is or contains a poisonous, toxic, inflammable, explosive or corrosive product or substance or other product or substance of a similar nature that he is satisfied is or is likely to be a danger to the health or safety of the public, or

(b) any product designed for household, garden or personal use, for use in sports or recreational activities, as life-saving equipment or as a toy, plaything or equipment for use by children that he is satisfied is or is likely to be a danger to the health or safety of the public because of its design, construction or contents,

or by deleting therefrom any product or substance the inclusion of which therein he is satisfied is no longer necessary."

Certain exemptions were made for products which might be hazardous but are already covered under Acts listed in Section 15:

"15.

This Act does not apply to any product or substance that is

(a) an explosive within the meaning of the Explosives Act;

(b) a cosmetic, device, drug or food within the meaning of the Food and Drugs Act;

(c) a control product within the meaning of the Pest Control Products Act; or

(d) a prescribed substance within the meaning of the Atomic Energy Control Act."

Conclusion

In summary, I believe these three pieces of legislation are the most significant advances in Canadian drug control and consumer protection in many years. As I indicated previously, it is too early to attempt to assess the impact of these changes, either on the industries affected, on drug prices or on the increased protection to the public. Time alone will tell how successful we have been in attaining the desired results. **[The End]**

The Fourth Dimension in Labeling: Trademark Consequences of an Improper Label—Part I

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I. Introduction

AS INDICATED BY THE TITLE,[1] this is an inquiry into the trademark ramifications of labeling. A concise statement of the metes and bounds of the problem may be had by a reference to two recent trademark cases. One is illustrative; one is critical.

First, in any inquiry into trademark registration, it is good to have at hand exactly what a trademark registration accomplishes, especially the policy objectives. A synoptic statement of those appears in a recent opinion of the Court of Customs and Patent Appeals, hereinafter CCPA, written by Judge Rich:[2]

> (T)he acquisition of the right to exclude others from the use of a trademark results from the fact of use and the common law, independently of registration in the Patent Office. . . . It is in the public interest to *maintain* registrations of tech-

[1] The other three main categories of consequences of label improprieties are: (1) criminal penalties such as fine and imprisonment, (2) injunctions or restraining orders against such behavior, and (3) seizure in a libel action of the offensively labeled commodity. See, for example, Rubenstein, "Your Label, Labeling and the Law," 16 FOOD DRUG COSMETIC LAW JOURNAL 356, 369 (1961).

[2] *Morehouse Manufacturing Corp. v. J. Strickland & Co.*, 160 USPQ 715, 720 (CCPA, 1969). This case will be discussed in some detail below.

nically good trademarks on the register so long as they are still in use. The register then reflects commercial reality. Assertions of 'fraud' should be dealt with realistically, comprehending, as the board did, that trademark rights, unlike patent rights continue notwithstanding cancellation of those additional rights which the Patent Office is empowered by statute to grant.

As is intimated in Judge Rich's remarks, certain kinds of conduct may well result in cancellation of federal rights in trademark registration—notwithstanding the fact that certain rights may remain. This is equally true with respect to trademark application for registration, and registration may be denied in the first instance.

As will appear in greater detail below, the concern here will be primarily with the latter of these, and it is thus useful to consider at the outset the impact that improper labeling may have on a party's right to register.[3] The attitude of the Patent Office is manifest in the following opinion:[4]

> As a condition precedent to registration, it is necessary that goods bearing the mark sought to be registered, be sold or transported in commerce which may lawfully be regulated by Congress. If the goods in question cannot enter the stream of commerce unless and until certain conditions including labeling requirements . . . are met, it follows that any shipments in commerce not in compliance therewith constitute 'unlawful shipments' in commerce from which no trademark rights can accrue to properly form a basis for 'use of a mark in commerce' which the Patent Office can properly recognize. . . .
>
> That is, a party may not enter commerce and seek registration unless and until he has fully complied with the particular Act of Congress which directly controls the commerce in such goods.

Thus, in *Stellar*,[5] the Patent Office Trademark Trial and Appeal Board, hereinafter the trademark appeal board or Board, raises and confronts an extremely viable and important issue. If their statement, as quoted, is to be taken at face value, one may find himself in the unfortunate position of having an *ab initio*[6] invalid trademark which is not entitled to registration. More unfortunately, if the label defect, for example, is not detected in the registration process, or if there is substantial delay between commencement of use of the mark and attempted registration, a party may find his rights seriously com-

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[3] See the Trademark Act of 1946, as amended; also known as the Lanham Act; 60 Stat. 427 and following. 15 U. S. C. 1051 and following; hereinafter cited by section only or as 15 U. S. C. —. See, for example, Sec. 1, 15 U. S. C. 1051; Sec. 23, 15 U. S. C. 1091.

[4] *In re Stellar International, Inc.*, 159 USPQ 48, 51 (POTT&AB, 1968). As to the statutory composition and authority of the Trademark Trial and Appeal Board, the trademark appeal board, or the Board, see, for example, Sec. 17 or 20; 15 U. S. C. 1067, 1070.

[5] See footnote 4, above.

[6] Literally, "from the beginning."

promised—the inevitable consequence of having a great deal of good will connected with a mark that is either unregistrable or subject to cancellation. Inadvertence and innocent error are poor defenses, for as is often stated: ignorance is no defense to a violation of law.

The task here, then, is to make inquiry to discover whether or not the picture is as bleak as it appears on first blush. It is one of attempting to fix the scope of the problem as it applies to labeling primarily and, further, of inquiring into the authority and wisdom of the Patent Office in its resolution of such an important issue.

II. Summary Analysis of the Problem

It seems useful to consider the scope of the types of label defects one might try to avoid and the consequences of such defects, if not avoided. Within the term "improper" or "defective" may appear varying degrees of "deception," "fraud," and "illegality." Cursory reflection will reveal that of all the possible types of such improper labeling, only a few will present any difficulty. From a practical standpoint, for example, it does not seem worthwhile to distinguish fraud from deception.[7] The scope of impropriety that may find itself the subject of criminal sanction is, of course, a function of legislative fiat, and, in this day and age, it is hardly possible to conjure up examples of the most innocently deceptive labels which are not subject to criminal sanction.[8] Indeed, labels may be illegal even though totally devoid of deception.[9] There are two reasons for keeping the potential breadth of impropriety in mind. First, the standard of legality is subject to almost instant change, and, second, the Patent Office isn't necessarily limited to only that with which it concerns itself today.

[7] For most purposes here the presence of an *intent* to receive will be immaterial. The problems associated with the improper use of "the letter R enclosed within a circle," Sec. 30, 15 U. S. C. 1111, has created some thorny problems. See, for example, *Independent Grocer's Alliance v. Zayre*, 149 USPQ 229, 230 (POTT&AB, 1966). While the improper use of the notice of registration is not illegal, it has often been urged as a fraud against the public, for example, to bar a registrant's rights in one respect or another. Such attempts have been largely unsuccessful. *Independent Grocer's* is a good summary.

[8] An example of one not subject to criminal sanction is "R in a circle," cited in footnote 7, above, is such a case. Compare 35 U. S. C. 292 re "patented" or the like.

[9] Such a case is presented by *Stellar*, footnote 4, above. In that case the illegality arose under Sec. 602 of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 362. That section provides that a cosmetic shall be misbranded unless an accurate statement of the net contents appears on the label. There is no requirement that anyone be deceived to give rise to illegality. For a more general proscription, see Sec. 4(a)(2) of the Fair Packaging and Labeling Act, 80 Stat. 1297 (1966).

There are three trademark-related consequences of a defective label. In addition to a refusal to register and the possibility of cancellation of a mark, already registered, there is the possibility of a refusal to enforce the rights of a registrant.[10] Such trademark-based sanctions may come into issue in two distinct types of proceedings, as ex parte or inter partes contests, and may arise either in the courts or before the Patent Office.

Registration is largely an ex parte proceeding, but may become an inter partes matter in one of several ways.[11] The forum for such a contest is usually the Patent Office, but courts may become involved on appeal from the Patent Office.[12]

The issue of whether to cancel a mark from the register[13] or whether to enforce a mark by appropriate remedy, on the other hand, will always be inter partes matters. Often the two issues just cited will be joined in a single case, and a registrant bringing an action against an infringer may well find himself in an unenviable position, with the court, for example, not only refusing to enforce his rights, but also acting favorably on a motion to cancel the registration.[14] As was just intimated, such inter partes proceedings may arise in either the courts or the Patent Office.[15]

The problem which has been most closely scrutinized and which is to be analyzed in detail here is the propriety of Patent Office refusal to register a mark which has been used in "unlawful commerce."[16] Such a Patent Office proceeding, which is often ex parte, cannot be viewed in a vacuum. The possibility, indeed the reality, of subsequent inter partes and extra-Patent Office[17] action should have considerable

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[10] See *Independent Grocer's*, footnote 7, above; *Dr. Nicholas C. Strey v. Devine's, Inc.*, (C. A. 7 1954) 217 F. 2d 187, discussed in detail, below.

[11] There are three such possibilities: (1) declaration of an interference, Sec. 16, 15 U. S. C. 1066; (2) concurrent use application, Sec. 2(d), 15 U. S. C. 1052-(d); (3) opposition, Sec. 13, 15 U. S. C. 1063. Generally, see Sec. 17, footnote 4, above.

[12] Generally, see Sec. 21, 15 U. S. C. 1071.

[13] There are really several registers: two trademark registers, a service mark register, and a collective mark register. Here, the last two will not be further considered. See Secs. 1, 3, 4, and 23 of the act, but note Sec. 26. The two trademark registers are quite distinct, as will be discussed in detail, below.

[14] Sec. 37, 15 U. S. C. 1119, provides that "In any action involving a registered mark the court may determine the right to registration, order the cancellation. . . ."

[15] See footnote 10, above.

[16] That term appears nowhere in the act, although the language calling for a "lawful use in commerce" appears in Secs. 2(d) and 23. The term is set apart to indicate that there is some question as to its meaning; see part V of this paper, below.

[17] The term, "extra-Patent Office" is used to refer to other regulatory action, for example, by the Food and Drug Administration.

influence on the course of action dictated. The purpose of the above discussion, then, is not so much designed to impress the non-trademark attorney with the fact that the area is complicated, as to lay the groundwork upon which a realistic analysis of the problem must rest.

In addition to possible subsequent inter partes and extra-Patent Office action, mentioned above, there are other practical considerations which bear on the scope of the present inquiry. For example, the likelihood of the Trademark Examiner getting too far afield in attempting to protect the public from applicant's misconduct is small. It would seem, a priori, that his role will be limited to refusal to register for misconduct which he is capable of detecting, for example, from an inspection of the specimen labels filed with the application.[18]

In this vein, the Patent Office seems to have limited the scope of his, and this, inquiry even further, and, at this writing, the Examiner will not be concerned with label improprieties that are not forbidden under an "Act of Congress."[19] Hence they will not be further discussed here.

The problem as thus limited is a relatively new one, and the law is sparse. In the past ten years or so, the problems associated with the accrual of trademark rights based on "unlawful" or "illegal use in commerce" have become increasingly thorny ones. The delimiation and resolution of a relatively newly-discovered area of Patent Office inquiry have been the source of concern. The task here, of course, is to attempt to determine whether the concern is a realistic one. Such a determination may be divided into four parts: (1) analysis of a rule which permits Patent Office inquiry into matters of non-Patent Office regulatory compliance, (2) the analysis of the agency interpretation and application of its rule, (3) the statutory and case authority for the rule as applied, and finally (4) the possibility of practical alternative techniques for the protection of the common good. In the final analysis, the real issue is the necessity for a watchdog stance on the part of the Patent Office in furtherance of what it deems to be public policy.

III. Rule 2.69

Since Rule 2.69 is the nexus of the inquiry, it will be helpful to have the specific language at hand:[20]

[18] See Trademark Rule 2.56. The Trademark Rules are Part 2 of Title 37 (Patents, Trademarks, and Copyrights) of the Code of Federal Regulations and will be hereinafter referred to only by number.

[19] See Trademark Rule 2.69; *Stellar*, footnote 4, above.

[20] See footnote 18, above.

When the sale or transportation of any product for which registration of a trademark is sought is regulated under an Act of Congress, the Office may, before allowance, make appropriate inquiry as to compliance with such act for the sole purpose of determining lawfulness of the commerce recited in the application.

While there is specific authority cited for the rule,[21] neither that authority nor the history of the rule is particularly revealing as to what its impact might be. For example, the following questions are not satisfactorily answered by a literal reading of the rule: (1) Which "Acts of Congress" are contemplated? The Sherman Act?[22] The Federal Food, Drug, and Cosmetic Act?[23] (2) What is to be done once appropriate inquiry has been made? Refuse registration? Inform the applicant of his non-compliance? Or, perhaps, inform the agency, for example, the Food and Drug Administration, within whose province the suspected violation falls? Reasonable minds might differ as to the correct answers to those questions—assuming such an answer exists at all.

As for the history of the rule, there is little to be said. It appears to have been first promulgated to take effect with a general renumbering and revision of the rules in 1955.[24] There appears to have been an old rule that might be the precursor of Rule 2.69, but there is little to be gained from an examination of the history of that rule, for there does not appear to be a case applying it.[25] For that

[21] See "Trademark Rules of Practice of the Patent Office with Forms and Statutes," p. 18 (1966) (available from the U. S. Government Printing Office). Rule 2.69 is said to "interpret or apply sec. 12, 60 Stat. 432; 15 U. S. C. 1062." That section merely provides for an examination of applications. The Commissioner's authority comes from Sec. 41, 15 U. S.C. 1123.

[22] 26 Stat. 209 (1890), 15 U. S. C. 1, 2.

[23] Title 21, U. S. C.

[24] 20 *Federal Register* 4797—4815 (1955).

[25] When the rules were revised and renumbered to take effect with the passage of the Trademark Act, footnote 3, above, Rule 109.141 appears. 12 *Federal Register* 3956 (1947). It was subsequently amended. 16 *Federal Register* 9440 (1951); 17 *Federal Register* 1218 (1952); 19 *Federal Register* 5357 (1954). That rule dealt with filing a certificate of clearance of labels dealing with meats, wines, and other alcoholic beverages. No apparent equivalent of old rule 109.141 appears in the proposed revision of 1955 (Footnote 24, above). In the rules text cited in footnote 21, above, Rule 2.69 is indexed under references to meats, wines, and other alcoholic beverages at pp. 119, 124, and 113, respectively.

The statutes dealing with those matters are somewhat revealing. See 27 U. S. C. A. Secs. 201-212, 49 Stat. 977 (1935); 21 U. S. C. A. Ch. 12, Secs. 603-623 (amended 1967). 27 U. S. C. 203(a) provides that it is unlawful to (1) import or (2) ship or sell certain alcoholic beverages without a prior permission by the Secretary of the Treasury. 27 U. S. C. 205(e) provides that it is unlawful to ship or sell "any distilled spirits, wine, or malt beverages in bottles," unless "bottled, packaged and labeled in conformity" with regulations, and goes on to provide that a *prior label approval* be secured before bottling or, in the proper case, removal from customs. Title 21, Ch. 12 is very similar. Apparently 21 U. S. C. 607(d) requires *preclearance* even of trademarks to be used

(Continued on the following page.)

matter, it was not until 1968, when the *Stellar*[26] decision was delivered, that the existence of such a rule was even acknowledged. *Stellar* will be the subject of a detailed discussion below.

IV. In re Stellar International, Inc.

There are four reasons why *Stellar* is vital to this discussion: (1) It is the latest Patent Office statement on the issue of the effect of the trademark user's unlawful entry into commerce. (2) It is the only case in which the lawfulness of the commerce is the *sole* issue. (3) As noted above, it is the only case where Rule 2.69 was cited and discussed. (4) Finally, it appears to give a fairly comprehensive statement of the Patent Office position on this important issue.

The case was an ex parte appeal from a refusal of the Examiner to register the mark, "JETFRESH," for an aerosol mouth freshener, the basis for that refusal being the absence of net contents on the labels filed with the application. The Examiner urged that in the absence of either the net contents on the label . . .[27]

> . . . and/or a verified statement by an authorized officer of the corporation that applicant was, in fact, complying with that Act (the Federal Food, Drug, and Cosmetic Act), at least as early as the filing date of the application, any use . . . in interstate commerce was not lawful . . . commerce which can serve as the basis for registration in the Patent Office.

The authority for the Examiner's position was found in Rule 2.69 and in Sec. 1 of the Trademark Act,[28] the latter of which states in part that:

> The owner of a trademark used *in commerce* may register his trademark under this Act on the principal register hereby established . . . . . (Italics added.)

The crucial question was the meaning of "commerce" since it is not qualified in the act by the word "lawful." Does the word "commerce" of necessity embrace the qualification that it be a "lawful" commerce? The trademark appeal board's apparently unqualified answer to that question has been previously quoted herein.[29]

In affirming the Examiner, the Board's reasoning took the following form: (1) The Commissioner of Patents has the authority

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(Footnote 25 continued.)
on meat labels. Needless to say, these are not ordinary labeling provisions, but see Sec. 505(b)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 355-(b)(6). Compare Sec. 502 of that act, 21 U. S. C. 352.

[26] See footnote 4, above.

[27] See footnote 4, above, p. 49. See Rule 2.33, listing the requirements for an application.

[28] See footnote 3, above.

[29] See footnote 4, above.

to make rules pursuant to Sec. 41 of the Act,[30] and thus Rule 2.69 was promulgated.[31] (2) To not act under the authority of the rule in the manner in which this particular Examiner did, would render the rule "ineffective and an inquiry thereunder would be nothing more than a waste of time and effort."[32] (3) "It seems evident that the term 'commerce' whenever and wherever used in the trademark statute must necessarily refer to 'lawful commerce';...."[33] (4) And, finally having reviewed three somewhat related cases previously resolved in the Patent Office,[34] the Board decided that the Examiner had authority to inquire into the regulatory compliance issue and, in the event that compliance was lacking, to refuse registration.[35]

In what might be interpreted as a conciliatory gesture, the Board also indicated that it was not concerned "with the imposition of criminal penalties,"[36] and that:[37]

> The authority under Rule 2.69 should, however, be exercised sparingly and only when the file suggests noncompliance with a regulatory act.

One such way that the file might suggest noncompliance would be "if specimen labels submitted with an application show *on their face* that the applicant has not complied. . . ."[38] (Italics added.)

Before delving further into the rule as interpreted and applied in *Stellar*, however, there are two further matters to be considered: (1) the statutory authority for the interpretation of the word "commerce" necessary to support the *Stellar* holding, and (2) the relatively scanty case law that is even remotely in point. Thus it is convenient, for the moment, to hold *Stellar* in abeyance.

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[30] See footnote 21, above.

[31] See footnote 4, above, at p. 50.

[32] See footnote 4, above, at p. 51.

[33] See footnote 4, above, at p. 51.

[34] *Ex parte H. Zussman & Son Company*, 111 USPQ 283 (Comr., 1956); *Coahoma Chemical Co., Inc. v. Smith* . . ., 113 USPQ 413 (Comr., 1957); *In re Taylor*, 133 USPQ 490 (POTT&AB, 1962). In regard to petitions to the Commissioner, see Rule 2.146.

[35] See footnote 4, above, at p. 52.

[36] See footnote 4, above, at p. 51.

[37] See footnote 4, above, at p. 51.

[38] See footnote 4, above, at p. 51. Also see footnote 9, above; Section 602(b)(2) has a proviso which reads in part: ". . . exemptions as to small packages shall be established, by regulations prescribed by the Secretary."

The Board's opinion at p. 50 acknowledges that the packages were "very small" and acknowledges an affidavit by the Vice President of applicant to the effect that the FDA was being consulted in this matter. The Board was not impressed, and seems to indicate at p. 52 that the subsequent use of applicant of such data on its label is additional reason for the validity of its holding.

The correctness of the Board's interpretation of the food law is not an issue here, except to the extent that it bears on the authority and wisdom of its entering into such an interpretation of that law in the first instance.

V. The Meaning of "Commerce" in the Trademark Act

Support is weak, indeed, for the proposition that, wherever used, the word "commerce" in the Trademark Act means "lawful commerce." There are at least two reasons for this lack of support. First, it flies in the face of a common rule of statutory construction, and, perhaps even more importantly, the two lone appearances of the phrase "lawful use in commerce"[39] in the act seem to be a historical fluke.

While those conclusions will require some explaining, it is necessary, in order to do so, to keep in mind that there is not one, but rather two, trademark registers[40]—principal and supplemental. Not only their purposes, but also the rights given thereunder are distinct.[41] And it must be remembered that a rule promulgated by the Patent Office is equally applicable to both trademark registers without further limitation[42]—no such limitation appears in Rule 2.69.

It is difficult to discuss the meaning of the phrase "lawful use in commerce" from a historical standpoint. In the first place, neither of its inclusions occurred until fairly late in the history of the act. Hence, there is not a background of interpretive pre-1946 case law to draw upon. Nor is the legislative history of either inclusion too clear.

Section 2(d), dealing with concurrent use, seems to have appeared in the act for the first time in 1941 as per its presence in a bill based upon American Bar Association recommendations.[43] In the same

[39] Secs. 2(d) and 23; 15 U. S. C. 1052(d) and 1091, respectively.

[40] See footnote 13, above. The principal register, Sec. 1, 15 U. S. C. 1051, is primarily for domestic use. The types of things registerable thereon as "marks" are strictly limited. This is in contrast with the supplemental register, Sec. 23, 15 U. S. C. 1091. The latter allows the registration of various techniques for distinguishing applicant's goods in commerce; for example, package configurations, labels. The purpose of such registration is to provide a U. S. registration upon which an applicant may base a foreign registration in those countries which do not recognize the doctrine of "secondary meaning" which provides some protection for such things here. See, for example, Hearings on H. R. 9041, House of Representatives Committee on Patents, Subcommittee on Trademarks, 75th Cong. 3d Sess., pp. 179-182 (1938). In that bill the supplemental register was Sec. 25.

[41] See Sec. 26, 15 U. S. C. 1094 limiting the applicability of certain sections of the Act, section by section, to the supplemental register. See also, footnote 40, above; footnote 46, below. In regard to the 1920 Act, it was once remarked in the Senate committee report: "This legislation has no effect on the domestic rights of anyone. It is simply for the purpose . . . of complying with legislation in foreign countries." *Chas. Broadway Rouss, Inc. v. Winchester Co.*, 300 F. 706, 713-14 (CA-2 1924).

[42] See footnote 11, above. Compare, for example, Rule 2.99 which is applicable to both types of application (concurrent registrations) with Rules 2.91(d), regarding interferences, and Rule 2.101, regarding opposition, which are not applicable to supplemental registration applications.

[43] Hearings on H. R. 102, H. R. 5461, and S. 895, House Committee on Patents, Subcommittee on Trademarks, 77th Cong.,

(Continued on the following page.)

bill, the phrase "lawful use in commerce" appears for the first time as a part of supplemental registration provisions.[44] It is this provision that seems to give the most clues as to the intended meaning of the phrase, even though it has been observed that, in general, the legislative history of that section is "not too enlightening."[45]

The basic provision for the supplemental register is Sec. 23. Therein it is pointed out that it is a continuation of the register "provided in paragraph (b) of section 1 of the Act of March 19, 1920. . . ."[46] Under that act, the equivalent of the term "lawful" had been the term "bona fide."[47] Why was the substitution made? The reason seems to be based on an unfortunate interpretation of the term "bona fide" as used in the 1920 act,[48] with that term being read to mean "exclusive," not "good faith."

(Footnote 43 continued.)
1st Sess., pp. 58—61 (1941). Three legislative drafts appear therein. Those are a "committee print," H. R. 102, and H. R. 5461. S. 895 is not reprinted; that bill, which had passed the Senate, was said to be identical to H. R. 102.

In the *Hearings*, above, at pp. 60—61, it appears that the "committee print" is the text of the A. B. A. proposals. According to that information, a revised draft was submitted to the A. B. A. Patent, Trademark and Copyright Section on Jan. 18, 1941, was further revised at a Washington, D. C. meeting on February 6, 1941, and was finally certified to and approved by the A. B. A. House of Delegates in Chicago on March 18, 1941. However, certain clerical errors have been said to be corrected in the "committee print," and minor changes made therein in Secs. 29 and 46, neither of which are applicable here. H. R. 5461 was said to be an essential duplicate of the "committee print," and, at least as far as the language of Secs. 2(d) and 23 are concerned, this appears to be accurate. The term, "lawful use in commerce," appears for the first time in those drafts.

There is some cause to doubt the accuracy of that information. In a response to an inquiry in regard to the reason for the language substitution, the Assistant to the Secretary of the A. B. A. Section, Mr. Durkee, wrote as follows:

"At the Indianapolis Annual Meeting, September 29—30, 1941, the Section approved an amended version of a Lanham bill. § 23 of the amended version, however, used the term 'bona fide' rather than 'lawful,' and no discussion appears in the Summary of Proceedings as to this specific portion of § 23 in the amended version.

"Subsequent to 1941 the Section discussed the proposed trademark legislation extensively, and suggested further amendments, but nowhere can I find that the Section considered § 23 further. . . .

"The Section records, however, do indicate that individuals were revising the bill without official action by the Section or ABA."

[44] *Hearings*, footnote 43, above, p. 20. Compare, *Hearings*, footnote 40, above. See also Hearings on H. R. 4744, same committee, 76th Cong., 1st Sess. (1939).

[45] *Ex parte Caron Corporation*, 100 USPQ 356, 358; 44 T. M. R. 336 (Comr., 1954).

[46] 15 U. S. C. 1091, citing 41 Stat. 533 (1920), 46 Stat. 155 (1930), 52 Stat. 638 (1938), 15 U. S. C. 121 (1939).

[47] See footnote 44, above.

[48] *Hearings*, footnote 40, above, p. 103. See also, for example, *Fortune Tobacco Co. v. Axton Fischer Tobacco Co.*, 22 USPQ 366, 369 (Comr., 1939); Halliday, footnote 50, below.

The exclusive use requirement for supplemental registration appears to have worked substantial hardship, and when the bills that eventually became the 1946 act were being considered, a prime desire on the part of some members of the bar was to be rid of that requirement. It is thus quite possible that the insertion of the word "lawful" for the term "bona fide" was nothing more than a manifestation of that desire.[49]

In a dissertation written only a few years after passage of the 1946 act, the gist of the present inquiry does not even seem to have been considered. Rather, it was argued that the introduction of the phrase "lawful use in commerce" in both Secs. 2(d) and 23 had precluded the interpretation of "lawful" to mean "exclusive."[50] Indeed, it would seem that two parties could hardly be entitled to *concurrent* registrations if each is held to the requirement of a year's *exclusive* use prior thereto.[51] At any rate, it is doubted that the fact that Secs. 2(d) and 23 had the only appearances of the term "lawful" is a historical coincidence.

Thus the question remains: Does "commerce," wherever used, mean "lawful commerce?" The answer to that would seem to depend on the answer to the question: Does "lawful use in commerce," as twice used in the act, mean "not in violation of an Act of Congress?" These two questions present a paradox, for, on the one hand, if "lawful" literally means commerce complying with all relevant requirements of law,[52] there would seem to be a good argument that such a limitation should not be read into those sections of the act in which it does not appear. The specific inclusion of that limitation in Sec. 2(d) would not seem to support the assertion that it was inadvertently omitted from other parts of that section.[53]

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[49] There is little but inference to support that conclusion. See footnote 43, above; footnote 50, below.

[50] Halliday, Walter J., "The Supplemental Register," 48 (1949). This is an unpublished dissertation for the J. S. D. at New York University. N. Y. U. call no. LD 3907, .L4—1950 H.2, 149 pp. Compare *Automatic Washer Co. v. Easy Washing Machine Corp.*, 98 F. Supp. 445, 451-52 (ND, NY, 1951), (89 USPQ 524).

[51] The year's use requirement may be waived; see the last full paragraph of Sec. 23.

[52] See the quotation from *Stellar*, above, corresponding to footnote 4. Once it has been decided to delve into the legality of the commerce, is there any good reason to limit the inquiry to *federal* law?

[53] See Sec. 2, 15 U. S. C. 1052. That section begins: "No trademark by which the goods of the applicant may be distinguished from the goods of others shall be refused registration on the principal register on account of its nature unless it. . . ." This section merits close study for those interested, but it is much too long to quote in its entirety here.

On the other hand, if "lawful" merely means something akin to "non-exclusive," this would give more weight to the argument used in *Stellar* that "commerce" must necessarily mean "lawful commerce."[54] That is to say that if the word "lawful," as twice used in the act in conjunction with "commerce," was never intended to mean "lawful" at all, there would seem to be a good argument, or at least a credible argument, perhaps, that the term, "commerce," where used, *does* in fact mean *"lawful* commerce" in a more conventional sense. This results, of course, from the conclusion that the term "lawful," where in fact used in the act, does *not* mean that which one might reasonably expect it to mean.

The upshot of an analysis of the legislative history of the act is that there is little authority to either support or refute, in a specific and concrete way,[55] the *Stellar* argument. The result of such a conclusion is that the issue is largely one of policy.[56] There are practical considerations as well. Both of these will be easier to discusss with a more thorough inquiry into the remaining case law.

VI. The Case Law

It has been noted that the case law concerning the legality of a trademark registrant's use in commerce is sparse. Three such cases were mentioned in *Stellar*.[57] It is useful to consider them in chronological order, and in some detail. All arose in the Patent Office.

Ex Parte H. Zussman & Son Co.

Zussman[58] was decided in 1956 on an appeal from the refusal of the Examiner to register the mark, "4 H'ers THOROBRED JEANS." There were two grounds for that refusal: (1) Under Sec. 2(a),[59] a mark is unregistrable if it "consists of or comprises . . . matter which may disparage or falsely suggest a connection with . . . institutions . . . ," such institution, of course, being the well known 4-H Club. (2) It was further urged that use of such a mark is in violation of a criminal statute[60] specifically forbidding unauthorized use of the 4-H symbol or a colorable imitation thereof, and that such use would preclude registration.

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[54] See footnote 4, above.

[55] See, for example, footnote 43, above.

[56] Here, an attempt will be made to try to ferret out policy by an analysis of the cases and the practical considerations rather than by attempted parsing of the statute. Compare footnote 53, above; with footnote 52.

[57] See footnote 34, above.

[58] See footnote 34, above.

[59] See footnote 53, above.

[60] 18 U. S. C. 707.

The Commissioner, in a very short opinion, agreed that the mark was unregistrable under Sec. 2(a) of the act, and affirmed the Examiner on the first ground.[61] The second, however, was rejected. Having pointed out that such a criminal statute, "requiring strict proof of violation," may forbid use of certain symbols, it was stated that:[62]

> It is neither necessary nor proper for the Patent Office to consider the applicability of this section to applicant's conduct. Registration is clearly prohibited by . . . 2(a) . . . . and the question of the propriety of use of a symbol . . . in violation (18 USC 707) . . . is outside the jurisdiction of the Patent Office.

Coahoma Chemical Co., Inc. v. Smith

It is interesting to note that while Rule 2.69 appears to have been in force at that time.[63] it was not mentioned in the decision, nor was it mentioned in *Coahoma,*[64] coming slightly over six months later. The absence of reference to the rule seems justified in *Coahoma,* however, insofar as that was an inter partes matter.[65] Little else can be said about that case, however, in such a straightforward manner.

There seem to be three applications, more or less, in issue. For purposes here, they can be referred to as Smith, HGC (Howerton Gowen Company, Inc.), and Coahoma.[66] The Smith application was filed May 10, 1950, and the mark registered on July 31, 1951.[67] HGC was filed April 19, 1950, and when a conflict developed between it and Smith, that application was transferred to Smith. That application is not necessary to the discussion here.[68] Coahoma filed application on June 11, 1950, and, because of conflicts with the Smith application (registration), it had not yet been registered.[69] Concurrent use application apparently was initiated by Coahoma in January, 1953. From facts that developed there, Coahoma, on December 7, 1953, filed a petition to have the Smith marks cancelled. Pending the outcome of that petition, the concurrent use proceedings were suspended.[70]

Three grounds were urged by Coahoma: (1) that it had the first *lawful* use of a pesticide trademark containing a reference to a panther, (2) that Smith did not own nor had he used the mark "BLACK

[61] *Zussman,* footnote 34, above, at p. 283.
[62] *Zussman,* footnote 34, above, at p. 284.
[63] See footnote 24, above.
[64] See footnote 34, above.
[65] See footnote 20, above.
[66] *Coahoma,* footnote 34, above, at p. 413.
[67] *Coahoma,* footnote 34, above, at p. 415; see also footnote 4.
[68] *Coahoma,* footnote 34, above, at p. 417: "Since there is no evidence of sales under the mark of Howerton Gowen Company, Inc. (HGC), for purposes of these proceedings . . . the filing date of the (Smith) . . . application is the earliest date upon which respondent can rely. . . ."
[69] *Coahoma,* footnote 34, above, at p. 414; see also footnote 2.
[70] See footnote 59, above; see also footnote 3.

PANTHER," as claimed, and (3) that Smith's registration had been granted as a result of his false and misleading statements.

This case is on appeal from the Examiner of Interference's granting of the Coahoma petition to cancel the Smith registrations. Of the three grounds, the first was rejected because of the criminal ramifications,[71] the second was accepted, and the resolution of the third does not appear, although it is closely linked to the second.[72]

Although complicated, the facts seem vital to an analysis of this case, and, while detailed, they have been condensed considerably. It is easier to take each of the applications, one at a time, and follow it through.[73] Taking Smith first, it appears from the opinion that use of the mark "BLACK PANTHER" was begun in March or April of 1950, and that notice of registration[74] was received as to North Carolina and federal pesticide acts[75] on the 25th of April and the 8th of May, 1950, respectively. At the time of this use and registration under the pesticide acts, it appears that Smith (as the son of the president, general manager and sole stockholder of a New York corporation) was operating a branch office of that corporation in North Carolina. Smith apparently considered the idea of the mark his own, but gave the corporation permission to use it. Still acting under this misconception,[76] he applied for registration of the mark in the Patent Office, in his own name, in May, just after receiving notice from the Department of Agriculture of the registration of his labels in compliance with the Federal Economic Poisons Act (FEPA).[77] As stated above, this application was allowed, and registration became a fact under the trademark act a little over a year later.

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[71] See footnote 68, above; see also footnote 9.

[72] *Coahoma*, footnote 34, above, at p. 414.

[73] The chronological recitation of the facts begins at p. 414 in regard to Coahoma; 415, Smith; and 416, HGC, respectively, in the opinion.

[74] Apparently under the state and federal economic poisons (pesticides) acts, registration of a pesticide by filing the name of the shipper, the pesticide name, copies of the shipping labels, use, etc. is *required* prior to any shipments. Such filing is acknowledged by a notice. However, it does not appear, at least as to the federal act, that there is a possibility of non-registration. The Secretary of Agriculture may protest a registration, but must register nevertheless. Whether there is a protestation or not, registration does not save the registrant from any violations of the act as to other matters. See, for example, 7 U. S. C. 135b(1)(a), (b). It would not seem to matter when the party receives the notice of registration, so much as when registration papers were filed. This latter data does not appear in the Commissioner's opinion. At any rate, respondent, Smith, does not appear to have contested the fact that some of his shipments were illegal under that act.

[75] See footnote 74, above.

[76] See the discussion corresponding to footnote 90, below.

[77] 7 U. S. C. 135 and following. See footnote 74, above.

In regard to the Coahoma application, first use of the mark "RED PANTHER" was alleged for March 1, 1950, although notice of FEPA[78] registration was not received until 79 days later. First interstate sale apparently took place on May 8, 1950. It was also noted that while intrastate sales in Mississippi were initiated in April and that state's pesticide act[79] went into effect in May, notice of registration thereunder was not received by Coahoma until June 15, 1950.[80] As stated above, trademark application was filed June 11, 1950.

The Commissioner summarized the facts as follows: (1) Smith never did comply with the FEPA. (2) Although the New York corporation (Smith's employer at that time) complied with the FEPA on May 8, 1950: (a) this was the same day as Coahoma's first interstate sale, (b) seven weeks after that corporation's first interstate sale, and (c) three weeks after its first intrastate sale.[81]

In resolving the issues raised by Coahoma, it held favorably for Coahoma, apparently,[82] on all three: (1) unlawful use, (2) ownership, and (3) false and misleading statements by Smith. The first issue was stated in three different ways before it was finally resolved. They do not all appear to be the same issue, and it is thus necessary to state all three to be sure to catch the full grasp of the holding.[83]

First:[84]

The question presented by this record seems to be one of first impression, namely, does the user of a trademark on goods which could not be lawfully shipped in interstate commerce acquire registrable rights superior to those of a later user whose goods were lawfully shipped....

Second:[85]

Stated another way, did ... a New York corporation, acquire any recognizable rights, either at common law or under the Federal trademark statute, as a result of its unlawful shipments by its North Carolina branch....

Third:[86]

Reduced to its simplest terms, the question is: May property rights be acquired as a result of unlawful acts?

The answer:[87]

The obvious answer to the question in its simplified form is in the negative.

[78] Federal Economics Poison Act, footnote 77, above.

[79] *Coahoma,* footnote 34, above, at p. 414.

[80] See footnote 79, above.

[81] *Coahoma,* footnote 34, above, at p. 417.

[82] It is difficult to determine to what extent each might be regarded as a "holding." See the quoted material corresponding to footnote 88, below.

[83] See footnote 82, above.

[84] See footnote 81, above.

[85] See footnote 81, above.

[86] *Coahoma,* footnote 34, above, at p. 418.

[87] See footnote 86, above. At this point, the opinion cites five cases, none of which were found binding. See footnote 10, above. *Zussman,* footnote 34, above, was not cited. Three of those cases will be discussed in detail, below. See also 55 Yale L. J. 842 (1946).

No decision in a trademark case has been found which is directly in point; but in other fields of the law which might reasonably be analogous, i.e. real property and personal property, where claimed ownership was based on acquisition by unlawful means, the principle is so well-established that citation of authorities is unnecessary.

Expressed in its most concise form, the conclusion reached herein is that use of a mark in connection with unlawful shipments in interstate commerce is not use of a mark in commerce which the Patent Office may properly recognize.

On the basis of this conclusion .... The petitions to cancel are granted.

The other issues were considered immediately thereafter; this language, too, is interesting:[88]

The other issues are in the nature of ex parte issues .... Since one of the issues formed the basis of the recommendation of the Examiner of Interferences ..., they will both be treated here even though the petitions to cancel have been granted on another ground.

Thus, as the issue of "ownership," it was "held,"[89] if that term can be used, that because Smith was an employee:[90]

It is clear beyond question, therefore, that respondent did not use or own the mark at the time he filed the application. . . .

That there is no property in an "idea" for a trademark, and that property rights in a trademark grow out of its use and not out of its mere adoption are principles too well-established to require citation of authorities.

Finally, as to the issue of whether Smith had made "false and misleading statements under oath to the Patent Office,"[91] it was determined[92] that such statements had been made, and that the registrations would not have issued,[93] "had the true facts been disclosed .... The registration was, therefore, void ab initio."

There is one final bit of dicta that is useful to quote, insofar as it bears on the issue of *ab initio* invalidity. Taken with the statements made in *Stellar*,[94] it results in some rather chilling conclusions:[95]

Registrations which are void ab initio should be cancelled without regard to the rights of the parties to the cancellation proceedings; but where, as here,

[88] See footnote 86, above.

[89] See footnote 82, above.

[90] *Coahoma*, footnote 34, above at p. 419.

[91] *Coahoma*, footnote 34, above, at p. 420.

[92] See footnote 82, above.

[93] See footnote 91, above.

[94] See the quoted material corresponding to footnote 4, above.

[95] As a matter of fact, this language appears to have had some substantial effect on the *Stellar* decision. There is a serious question as to whether there is an error in that statement. Perhaps the word "not" should follow ". . . ab initio should . . . ." This, of course, would change the whole tenor of the statement.

There are at least two reasons for that conclusion as to whether the language is a typographical error or oversight. First, the sentence as it now reads does not make sense; the word, "but," as it now reads is inappropriate. Also the modified statement would be more in line with the philosophy set forth in *Morehouse*, corresponding to footnote 2, above. It would be unfortunate if *Stellar* were based on a misprint, if only in part.

damage to the petitioner (Coahoma) is presumed, cancellation of the registrations will be ordered.

Prior to an analysis of these cases, it will be useful to consider the third case relied on in *Stellar,* mentioned above,[96] and to consider three cases which were, to some extent, relied on in *Coahoma.*[97] Then, perhaps, Rule 2.69 can be seen in context.

In re Taylor

The *Taylor*[98] case appears to be the first time that the issue of the legality of commerce came before the trademark appeal board.[99] Here, the applicant was appealing from refusal to register the mark "CHUCK-A-BURGER," "for various restaurant and take-out food items including hamburgers, sandwiches, salads, desserts . . . ."[100]

There were four grounds of rejection: (1) that the mark was the common descriptive name of the item for which the mark was to be used, (2) the specimens on file (labels, etc.) did not show lawful use in commerce, (3) there did not appear to be interstate commerce, and (4) finally, the applicant refused to name the "salads, desserts, and non-alcoholic drinks."

The first and fourth grounds of refusal are not important here except to the extent that, in affirming the Examiner on those grounds, the Board weakened the necessity for its holding on the second and third grounds.[101] Apparently, the Examiner was overruled on the third ground, for the unlawful commerce which precluded registration on the second ground was arrived at by an interpretation of the Federal Food, Drug, and Cosmetic Act, Sec. 403(e).[102] That section, in conjunction with Sec. 301(b)[103] and Sec. 303,[104] makes it a criminal offense to introduce food into interstate commerce, if in package form, unless its label bears certain information. This information was found lacking on the submitted labels.[105] This led the Board to the conclusion that:[106]

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[96] *Taylor,* footnote 34, above.

[97] See footnote 87, above.

[98] See footnote 96, above.

[99] See footnote 4, above.

[100] *Taylor,* footnote 34, above, at p. 490.

[101] The board almost seems to go out of its way to overrule the Examiner on the third ground in order to be able to rule on the issue of a violation of a law regulating interstate commerce.

[102] 21 U. S. C. 343(e).

[103] 21 U. S. C. 331(b).

[104] 21 U. S. C. 333.

[105] See footnote 18, above.

[106] *Taylor,* footnote 34, above, at p. 491. Here, too, as in *Stellar,* it was urged that the statute in question had not been violated. The issue was one of whether the goods in question were "in package form" as required by Sec. 403(e) of the food law; see footnote 102, above. It was also urged in applicant's appeal brief that, in any event, a menu containing the required

(Continued on the following page.)

The specimens filed at the time of application are not in compliance with the Federal Food, Drug, and Cosmetic Act, and their use in interstate commerce cannot be construed to be a lawful use. Therefore, such use cannot afford a basis for federal registration.

It is unfortunate that the Board did not cite any authority for this proposition; neither *Zussman,*[107] nor *Coahoma,*[108] nor Rule 2.69,[109] nor any other. This would seem to weaken its value as support for the *Stellar*[110] holding. That leaves only *Coahoma* in favor; *Zussman* was contra. With that situation, then, it seems especially appropriate to examine some of the authority relied on in *Coahoma.*[111]

Of the three cases to be discussed here,[112] *Levi* and *Coffin Redington* arose on appeal from the Patent Office.[113] *Strey*, however, presents, for the first time here, a situation which did not arise in, nor directly concern, the Patent Office. All are inter partes matters.

Levi & Co. v. Uri

In the *Levi* case, the controversy centered around the propriety of a label for a rye whisky which had been labeled as "pure." The whisky had, in fact, been a blend, but in spite of that, there was no illegality connected with such mislabeling. With passage of the "pure food act," appellee had changed his labels to comply with that law.[114]

(Footnote 106 continued.)
information as per Sec. 403(e) accompanied all take-out orders. See Application No. 62, 808, filed November 19, 1958: Exhibit A, a copy of the menu; p. 4 of the appeal brief; and "Appellant's Suggestions re Section 403 of *The Federal Food, Drug, and Cosmetic Act,*" filed after argument. Here, again, the correctness of the Board's interpretation of the law is not in issue. See footnote 38, above.

[107] See footnote 34, above.

[108] See footnote 34, above.

[109] See footnote 20, above. See also footnote 87, above.

[110] See, for example, footnote 4, above, and the corresponding quoted matter.

[111] See footnote 87, above. The cases are *Levi & Co. v. Uri,* 31 App. D. C. 441 (CA D. C. 1908); *Coffin Redington Co. v. Turner,* 46 App. D. C. 449 (CA D. C. 1917); *Locatelli, Inc. v. Locatelli Packing Co.,* 97 USPQ 305 (Comr., 1953); *Dr. Nicholas C. Strey v. Devine's, Inc.,* 103 USPQ 289 (CA-7 1954); and *Jackman v. Calvert Distillers Corporation of Mass.,* 46 USPQ 289 (Mass. Sup. Ct. 1940).

As was pointed out in *Coahoma,* the *Jackman* case, above, is rather complicated and the issue of illegal sales is but one of many. Also, federal law does not seem to be considered; that case will not be further considered here.

The *Locatelli* case is of interest insofar as it appears to be the rare situation where proof of a violation of law was a fact prior to considering whether it would affect trademark rights, and, as was pointed out in the *Coahoma* footnote, the remark concerning unlawful use is clearly dicta.

[112] See footnote 111, above.

[113] Sec. 21, 15 U. S. C. 1071 provides for such review at present.

[114] Federal Food and Drugs Act of June 30, 1906, 34 Stat. 768.

In both *Levi* and *Coffin Redington,* the appeal arose from a Patent Office interference proceeding in which a first user had been successful in displacing a registrant.[115] In both cases, then, the first to register was contesting being so displaced. The court in *Levi* held that the Patent Office had been in error in allowing an improper first use to displace a proper later use:[116]

> It is our conclusion that, because of misleading statements on the labels containing the mark, appellee can claim no property rights therein and is not entitled to claim benefits of the trademark act.

Coffin Redington Co. v. Turner

In *Coffin Redington,* apparently, there was no unlawful commerce either, for the labeled commodity was a cosmetic preparation.[117] It was urged that those preparations were falsely labeled, and the appellee refused to testify to the compositions thereof for purposes of ascertaining whether, in fact, this was the case. Here too, then, the court held that the Patent Office had been in error in considering such improper use, and, in reversing, it relied heavily on *Levi,* above, stating that the Patent Office should not recognize a right to register a mark where a court of equity would deny enforcement of such a mark were it registered.[118] Needless to say, these are far-reaching conclusions.[119]

Strey v. Devine's, Inc.

It is surprising that forty years passed before such an issue arose again in such a direct way.[120] In *Strey,* however, mere misrepresentation was not the issue, for, in that case, both state and federal laws were held to have been violated by the party seeking to enforce trademark rights.

The plaintiff in *Strey* was seeking to enforce his rights against an infringing trademark. The defendant, among other things, was urging that whatever rights the plaintiff might have should not be enforced because he had been and was engaged in commerce in violation of law. In Illinois, on the one hand, it is illegal for a

[115] Sec. 16, 15 U. S. C. 1066; Rules 2.91 and following are the present authority for such a proceeding.

[116] *Levi,* footnote 111, above, at p. 446.

[117] Compare footnote 114, above. Cosmetics were not covered until passage of the present Act in 1938.

[118] *Coffin Redington,* footnote 111, above.

[119] There is a substantial distinction between refusing to register, ex parte, a mark where there has been some improper conduct, for example, in use of a label, and refusing to displace a first registrant with one whose prior use is based upon such misconduct. Compare Sec. 19, 15 U. S. C. 1069. See also footnote 95, above, and the discussion corresponding thereto.

[120] *Strey,* footnote 111, above.

chiropodist to represent that he is a medical doctor by using the title "Dr.," which appeared on the labels. On the other hand, federal law was allegedly violated by the failure to list on those labels the components of plaintiff's foot preparation.[121]

The court regarded such misconduct as grounds for not enforcing the rights of the plaintiff,[122] but the holding is somewhat weakened by the fact that the court also found that neither the labels, the containers, nor the marks physically resembled each other, that there was no real competition between the parties, and that the two marks, "KULE-FUT" and "KOOL-FOOT," merely have the same pronunciation.

There are some interesting ancillary issues raised by the facts in that case. For example, the registration sought to be enforced was not on the principal, but rather on the supplemental, register.[123] It will be recalled that on the latter, there is at least a literal requirement of lawful use in commerce. That language was not considered.

It is unfortunate, too, that the possibility of cancellation of the plaintiff's mark was not considered,[124] for the resolution of that issue would have had an important bearing on the wisdom of the approach of the Patent Office in dealing with the issue of illegal commerce. There is a possibility that, had the issue been raised, the court would have disposed of the case in exactly the same manner in which it did. This matter, however, will be discussed in more detail below.[125]

At this point, then, a wide variety of factual situations have been presented. Their resolution by the Patent Office and the courts has been accomplished in a number of ways. It remains to attempt to put the trademark user on notice as to where he may stand today.

[To Be Continued in the August Issue]

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[121] 21 U. S. C. 352(a), 352(e)(1)(A)(ii).

[122] *Strey*, footnote 111, above, at p. 290.

[123] See Part V, above, in general, and, specifically, footnotes 40, 41, and 43, above.

[124] Sec. 37, 15 U. S. C. 1119 provides that a court may order the cancellation of a mark or "otherwise rectify the register with respect to the registrations of any party to the action."

[125] It may be said at this point that it does not seem necessary for a court to cancel a registration on the basis of a label impropriety, for example, if such impropriety may be corrected and is not some sort of a blatant fraud. Indeed, even then there may be a 5-year bar. See Sec. 15, 15 U. S. C. 1065, but compare Sec. 24, 15 U. S. C. 1092, providing that no such bar is applicable to a supplemental registration.

BOOK REVIEW

Fundamental Principles and Objectives of a Comparative Food Law: Volume 3, Elements of Motivation and Elements of Qualification. By E. J. Bigwood, Director of the Food Law Research Centre of the Institute of European Studies of Brussels University, and A. Gerard, a Belgian lawyer and a member of the Food Law Research Centre. 240 Pages. S. Karger, Basel, Switzerland and White Plains, N. Y. 10602. 50 Swiss Francs—$12.00 U. S. Currency, plus $1.00 postage. Reviewed by Franklin M. Depew.

This book, the third volume in a series, continues the comparison of various provisions of the food laws of a number of European countries with each other and with those of the United States and Canada. In accordance with the plan set forth in Volume 1, these provisions are discussed in the present volume under two basic categories: Elements of Structure —fundamental character of the law and power to make regulations; and Institutional Elements —rules governing the drafting of regulations. In preparing this volume, the authors, Messrs. Bigwood and Gerard, collaborated with Mr. J. E. S. Ricardo, Barrister-at-Law, Inner Temple, London, and Mr. V. Brandts, a German lawyer, both of whom have joined the team of the Food Law Research Centre.

This volume discusses fully the theories and general concepts of the food laws of the various countries, and then reviews in detail the several methods adopted for the preparation of regulations, both administrative and scientific, including the methods whereby interested parties can present their views. The volume then reviews the procedures for the approval of food additives and the defining of food standards. The history and description of these important aspects of the food laws of these countries make valuable reading for anyone interested in complying with these laws or in furthering their harmonization.

In the first pages of their analysis of the elements of structure, the authors discuss further the system of abuse or of negative lists, which recognizes as lawful any additive substance or any technological treatment not expressly prohibited by some regulation; and

the system of prohibition or of positive lists which only recognizes as lawful additions to foods, those which have been expressly authorized beforehand by some regulation. It is pointed out that legislation of the latter kind runs the risk of stagnating in a rigid conservatism prejudicial both to progress and to the interest of everyone. A mixed system is suggested whereby the additive products which are of an exclusively synthetic nature would be subject to the principle of prohibition or positive lists, while the additives which exist in a natural state would be controlled in accordance with the principle of abuse or negative lists. This proposal will undoubtedly stimulate discussion among scientists here in the United States and throughout the world.

COMMISSIONER OUTLINES FDA POLICY

In an address to the Midwest Pharmaceutical Advertising Club on June 23, 1970, FDA Commissioner Charles C. Edwards expressed the hope that there will be a continuing dialogue between FDA and industry in the "new world" of the 1970's. Referring to his meeting with the Congressional Subcommittee on Inter-Governmental Relations, Dr. Edwards said of FDA's new platform and philosophy: "The American people merit a strong, independent, scientifically sound, well managed, well supported FDA in order that vital public interests can be protected. FDA shall be a balanced institution based on scientific competence and fair administration of regulatory law. FDA will be responsive to human concern and the needs of the public health through appropriate dissemination of scientific information to professionals, educational institutions, and other arms of government."

In order to promote industry-FDA dialogue, Dr. Edwards said that the possibility was being explored of appointing a communications advisory committee which would be made up of communications experts from FDA's various publics. Another cooperative effort is a new ad hoc committee consisting of FDA staff members and PMA representatives, which met for the first time in Washington to begin the joint development of guidelines for improving the Investigational New Drug process.

Dr. Edwards stressed that FDA's policy is to be "firm but fair," and indicated that a strong effort will be made to attract qualified scientific personnel, and to cut through the red tape of both industry and FDA.

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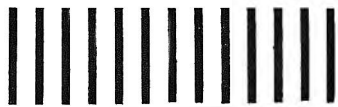

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