654 F.Supp. 568
United States District Court,
S.D. New York.

AMERICAN HOME PRODUCTS CORPORATION, Plaintiff,
v.
JOHNSON & JOHNSON, McNeilab, Inc., Saatchi & Saatchi Compton, Inc., and Kallir Philips Ross, Inc.

No. 85 Civ. 4858 (WCC).
|
Feb. 25, 1987.
|
As Amended April 1, April 6 and April 7, 1987.

Drug manufacturer sued for injunctive and other relief for competitor's alleged violations of Lanham Act, of New York General Business Law, and of common law of unfair competition. Competitor counterclaimed for plaintiff's alleged violations of Lanham Act and of New York statutory and common law. The District Court, William C. Conner, J., held that: (1) drug manufacturer, in providing physicians with "safety profiles" of pain relievers manufactured by it and its competitors, could not list only those areas of comparison where its pain reliever was allegedly more safe than competitors' products; (2) drug manufacturer's claim, that its pain reliever had safety profile superior to that of competing products, was within tolerable range of commercial puffery; (3) advertisement, which suggested that pain reliever manufactured by defendant was pain reliever hospitals used most, was not "false or misleading," though defendant neglected to mention that it supplied pain reliever to hospitals at very low prices; and (4) advertisement, suggesting that most hospitals recommended pain reliever found in analgesic manufactured by plaintiff, was misleading and unfair, for purpose of defendant's Lanham Act counterclaim.

So ordered.

West Headnotes (25)

[1] Antitrust and Trade Regulation
Comparisons;Comparative Advertising

Advertisement comparing side effects associated with each of three analgesics, which correctly identified side effects associated with each, but which conveyed false impression about comparative frequency of side effects associated with each, constituted "misleading advertisement" under the Lanham Act. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

2 Cases that cite this headnote

[2] Antitrust and Trade Regulation
Comparisons;Comparative Advertising

In providing physicians with "safety profiles" of various analgesics, drug manufacturer could not list only those areas of comparison where its analgesic was allegedly more safe than competitors' products without violating Lanham Act; circular created unacceptable potential for misleading even the professional audience at which it was directed. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

Cases that cite this headnote

[3] Antitrust and Trade Regulation
Comparisons;Comparative Advertising

Drug manufacturer's claim, that its analgesic had safety profile superior to competing analgesics, was within tolerable range of commercial puffery for purpose of Lanham Act, where manufacturer's product was somewhat superior to competing products in not causing certain adverse side effects; fact that manufacturer's product was allegedly somewhat inferior with respect to causing other adverse side effects was immaterial, as medical professionals to whom this claim was directed were likely to view such generalized comparisons with healthy skepticism. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

5 Cases that cite this headnote

[4] Antitrust and Trade Regulation

Consumer Data and Market Research; Tests and Surveys

Parties to Lanham Act action who wish to conduct surveys to determine how challenged advertisement is interpreted by public, should first submit proposed questions for inter partes challenge and court approval before incurring substantial expense of conducting interviews that might produce only useless results. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

1 Cases that cite this headnote

[5] Antitrust and Trade Regulation

Comparisons;Comparative Advertising

Though every statement in drug manufacturer's advertisement was literally correct, advertisement unfairly created impression that competitor's product and aspirin were comparable in their gastrointestinal and allergenic effects, contrary to Lanham Act, where statements followed title and photograph linking two drugs. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

Cases that cite this headnote

[6] Antitrust and Trade Regulation

Comparisons;Comparative Advertising

Advertisement, which suggested that analgesic manufactured by defendant helped to relieve pain without "stomach irritation" associated with aspirin or plaintiff's product, was not false for purpose of plaintiff's Lanham Act claim, where medical evidence tended to show that defendant's product had less "objective" gastrointestinal side effects, notwithstanding that neither product was associated with greater "subjective" gastrointestinal symptoms. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

1 Cases that cite this headnote

[7] Antitrust and Trade Regulation

Comparisons;Comparative Advertising

Advertisement, which suggested that analgesic manufactured by defendant helped to relieve pain without stomach irritation associated with aspirin or plaintiff's product, tended to suggest that plaintiff's product caused as much stomach irritation as aspirin, for purpose of plaintiff's Lanham Act suit. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

Cases that cite this headnote

[8] Antitrust and Trade Regulation

Comparisons;Comparative Advertising

Advertisement, which suggested that analgesic manufactured by defendant helped to relieve pain without stomach irritation associated with aspirin or even plaintiff's product, did not falsely suggest that plaintiff's product caused as much stomach irritation as aspirin, for purpose of plaintiff's Lanham Act suit. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

Cases that cite this headnote

[9] Antitrust and Trade Regulation

Comparisons;Comparative Advertising

Advertisement, which suggested that analgesic manufactured by defendant was at least as potent of a pain reliever as any other drug available without prescription, was simply not true, for purpose of competitor's Lanham Act claim, where competitor's drug was substantially more effective in treatment of severe pain. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

2 Cases that cite this headnote

[10] Antitrust and Trade Regulation

Particular Cases

Advertisement, which suggested that pain reliever manufactured by defendant was pain reliever hospitals used most, was not "misleading," for purpose of competitor's Lanham Act claim, though defendant

neglected to mention that it supplied pain reliever to hospitals at very low prices. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

Cases that cite this headnote

[11] Antitrust and Trade Regulation
Comparisons;Comparative Advertising

Advertisement, in which average consumer was depicted as saying that he had used aspirin-based pain reliever manufactured by plaintiff and that it did not upset his stomach, did not falsely suggest that plaintiff's drug caused less stomach distress than nonaspirin pain relievers, for purpose of competitor's Lanham Act counterclaim. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

2 Cases that cite this headnote

[12] Antitrust and Trade Regulation
Particular Cases

Advertisement, suggesting that 70,000 doctors recommended pain reliever manufactured by plaintiff, did not create false impression that most doctors recommended pain reliever manufactured by plaintiff, for purpose of competitor's Lanham Act counterclaim, though plaintiff neglected to mention that there were approximately 700,000 doctors in United States. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

Cases that cite this headnote

[13] Antitrust and Trade Regulation
Particular Cases

Advertisement, suggesting that 70,000 doctors recommended pain reliever manufactured by plaintiff, was not false or misleading for purpose of defendant's Lanham Act counterclaim, though plaintiff neglected to mention that it had supplied doctors with pain reliever free of charge. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

Cases that cite this headnote

[14] Antitrust and Trade Regulation
Particular Cases

Advertisement, suggesting that most hospitals recommended pain reliever found in analgesic manufactured by plaintiff, was misleading and unfair, for purpose of competitor's Lanham Act counterclaim, where plaintiff neglected to mention that other analgesics also contained same pain reliever, and that hospitals had actually recommended other such analgesic rather than plaintiff's product. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

1 Cases that cite this headnote

[15] Antitrust and Trade Regulation
Advertising, Marketing, and Promotion

Violation of Lanham Act is established by proving either that advertisement is literally false, or that it has a tendency to mislead or deceive. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

1 Cases that cite this headnote

[16] Antitrust and Trade Regulation
Advertising, Marketing, and Promotion

In determining whether advertisement is "misleading" under the Lanham Act, court must first consider its literal meaning, and then determine whether it conveys to particular audience at which it was directed any implied message beyond its literal meaning. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

1 Cases that cite this headnote

[17] Antitrust and Trade Regulation
Advertising, Marketing, and Promotion

Advertisement is "misleading," for purposes of Lanham Act, where it is likely to mislead a not insubstantial number of target

audience. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

Cases that cite this headnote

[18] Antitrust and Trade Regulation
Advertising, Marketing, and Promotion

Fact that advertisement contains definition or disclaimer which purports to change apparent meaning of claims and render them literally truthful will not remedy misleading nature of claims, for Lanham Act purposes, where definition or disclaimer is so inconspicuously located or in such fine print that readers tend to overlook it. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

4 Cases that cite this headnote

[19] Antitrust and Trade Regulation
Consumer Data and Market Research; Tests and Surveys

Meaning of advertisement to its target audience may be established by properly designed and conducted surveys, for purpose of Lanham Act action. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

Cases that cite this headnote

[20] Antitrust and Trade Regulation
Consumer Data and Market Research; Tests and Surveys

Probative value of survey, in establishing meaning of advertisement for purpose of Lanham Act challenge, depends entirely upon its fundamental fairness and objectivity, on whether it is properly "filtered" to screen out those who got no message from advertisement, on whether survey questions are directed to real issues, and on whether questions are leading or suggestive. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

9 Cases that cite this headnote

[21] Antitrust and Trade Regulation
Advertising, Marketing, and Promotion

Advertisement that cites as authorities sources that do not support ad's claims is "false and misleading," for purpose of Lanham Act. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

1 Cases that cite this headnote

[22] Antitrust and Trade Regulation
Advertising, Marketing, and Promotion

Government has strong public interest in prevention of misleading advertisements, particularly where over-the-counter drugs are concerned.

5 Cases that cite this headnote

[23] Constitutional Law
False or Deceptive Claims; Misrepresentation

Government's interest in preventing misleading advertisements prevails over advertiser's right of commercial speech, where advertisement is in fact misleading. U.S.C.A. Const.Amend. 1.

1 Cases that cite this headnote

[24] Equity
He Who Comes Into Equity Must Come with Clean Hands

Defense of unclean hands can be established in Lanham Act action only by clear, unequivocal and convincing evidence. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

6 Cases that cite this headnote

[25] Antitrust and Trade Regulation
Delay in Assertion of Rights;Laches

Defense of laches should be sparingly applied in Lanham Act action. Lanham Trade-Mark Act, § 43(a), as amended, 15 U.S.C.A. § 1125(a).

Cases that cite this headnote

Attorneys and Law Firms

***571** Arnold & Porter, Washington, D.C., Parker Auspitz Neesemann & Delehanty P.C., New York City, for plaintiff; Stuart J. Land, Steven P. Lockman, Washington, D.C., Jack C. Auspitz, New York City, of counsel.

Patterson, Belknap, Webb & Tyler, New York City, for defendants; David F. Dobbins, Gregory L. Diskant, of counsel.

OPINION AND ORDER

WILLIAM C. CONNER, District Judge:

This lawsuit represents a major battle in an endless war between two titans of the over-the-counter ("OTC") drug industry, in which each accuses the other of falsity in its advertising claims of efficacy and safety. Small nations have fought for their very survival with less resources and resourcefulness than these antagonists have ***572** brought to their epic struggle for commercial primacy in the OTC analgesic field.

American Home Products Corporation ("AHP") which, through its Whitehall Laboratories, Inc. ("Whitehall") subsidiary, markets the OTC analgesic ibuprofen under its trademark Advil, brought this action against Johnson & Johnson ("J & J") and its wholly-owned subsidiary McNeilab, Inc. ("McNeil") which markets the competitive OTC analgesic acetaminophen under the trademark Tylenol, as well as McNeil's advertising agencies, claiming falsity in widely published printed materials and television commercials linking ibuprofen with aspirin and unfavorably comparing both to acetaminophen in the respect of causing adverse side effects. J & J and McNeil have counterclaimed against AHP for alleged falsity in its comparative advertising of Advil and two of its other OTC analgesic products, Anacin, which is a mixture of aspirin and caffeine, and Anacin–3, which, like Tylenol, is acetaminophen.

The claims of both sides are based upon Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), sections 349(h) and 350–d(3) of the New York General Business Law, and the common law of unfair competition. Federal subject matter jurisdiction is based upon 15 U.S.C. § 1121, 28 U.S.C. §§ 1331 and 1338(a) and pendent jurisdiction.

The trial lasted four weeks, and involved the in-court testimony of 22 witnesses, many of them world-renowned physicians and medical researchers specializing in pharmacology, nephrology, hepatology, gastroenterology, hematology, epidemiology, and more particularly in the systemic effects of analgesics. The testimony of 37 additional witnesses was presented by deposition.

Many hundreds of exhibits, filling eight file drawers, were received in evidence, most of them copies of technical articles, couched in the arcane language of medical science, packed with numerical data and embellished with graphs and tables. Because many of these exhibits were merely "dumped" into evidence with only the briefest discussion by a witness, or none at all, the Court has not undertaken the mountainous task of reading all of them, but has confined its review to those which the parties deemed sufficiently important to cite in their briefs or proposed findings.

Almost a thousand pages of post-trial briefs and proposed findings were filed. But before the reply briefs had even been received by the Court, the attorneys for one of the parties sent a letter to the Court urging a prompt decision because the opposing party had recently resumed the broadcasting of certain challenged television commercials which it had voluntarily suspended in order to obtain a continuance of the trial.

Even the briefest discussion of all of the evidence considered would require an opinion thousands of pages in length which would never be read by anyone other than the parties, and which would make it impossible to satisfy counsel's expressed desire for expedited resolution of the controversy. The Court therefore will merely state in summary fashion its findings of fact pursuant to Rule 52, Fed.R.Civ.P., without a detailed analysis of the supporting evidence.

Background

Aspirin

The first OTC analgesic was aspirin (acetylsalicylic acid), which was introduced in 1899 and which, either in pure form or in various mixtures, monopolized the OTC analgesic market for over half a century. Aspirin is classified as a non-steroidal antiinflammatory drug ("NSAID"). Like all NSAIDs, its primary mechanism of action is to inhibit the body's normal production of prostaglandins, a family of substances synthesized by enzyme action in cells throughout the body and having various systemic functions or effects. One of the prostaglandin effects is sensitization of nerve endings to pain and another is inflammation of the joints. Thus prostaglandin inhibition quite effectively reduces pain and inflammation. However, since prostaglandins perform a number of beneficial functions, such as protection of the mucous ***573** lining of the gastrointestinal tract, vasodilation—which enhances blood circulation, particularly to the kidneys—and platelet aggregation (blood clotting), NSAIDs tend to cause gastrointestinal irritation and ulceration, renal dysfunction and anti-hemostasis (prolongation of bleeding).

These adverse side effects of aspirin, although not discovered for many years after its introduction, are now well known and undisputed. Indeed, many scientists have expressed the view that if a new drug application ("NDA") for OTC aspirin were now presented to the Food & Drug Administration ("FDA"), it would not be approved.

Aspirin is marketed OTC by many companies. For example, it is sold in pure form under the well-known trademark Bayer by Sterling Drug Co. Plaintiff AHP markets a mixture of 80% aspirin and 20% caffeine under the trademark Anacin.

Acetaminophen

The second OTC analgesic, acetaminophen (N-acetyl-para-aminophenol), was first widely marketed in the United States in the 1950's, although its properties had been discovered many years earlier. It reduces pain by elevating the pain threshold, although its mechanism of action is not fully understood. It also functions as an antipyretic by action on the hypothalamic heat-regulating center. However, unlike aspirin, it has no significant inhibitory effect on prostaglandin synthesis outside the central nervous system, nor any significant anti-inflammatory effect. Thus it is not an NSAID.

It is markedly superior to aspirin in its relative freedom from the adverse side effects of gastrointestinal irritation or ulceration and prolongation of bleeding. At massive overdoses, it can cause serious or even fatal hepatotoxicity, especially in chronic alcoholics or others with pre-existing liver damage.

It is marketed OTC by defendant McNeil in 325 mg. tablets under its trademark Tylenol and in 500 mg. capsules or "caplets" under the trademark Extra-Strength Tylenol. The FDA-approved package instructions for the latter product recommend the taking of two capsules (1,000 mg. or 1 g.) three or four times a day but no more than eight tablets (4 g.) in any 24–hour period.

It is also marketed OTC by plaintiff AHP under its trademark Anacin–3 and by Bristol-Myers under its trademark Datril. However, aggressive marketing and massive advertising by McNeil have given Tylenol a dominant position among the non-aspirin OTC analgesics.

Ibuprofen

Ibuprofen is an NSAID which was developed by Boots Pharmaceutical ("Boots") in Great Britan in the 1960's. Upjohn Company obtained from Boots a license to market ibuprofen in the United States, and in 1974 introduced a prescription ibuprofen product under its trademark Motrin.

Ibuprofen functions, like other NSAIDS, by inhibiting prostaglandin synthesis. Thus like aspirin, it is very effective in relieving pain and inflammation, and has the same types of side effects, although it is significantly more benign than aspirin in the respect of gastrointestinal irritation and anti-hemostasis.

AHP, McNeil and others sought licenses to market an OTC ibuprofen product in the United States. AHP succeeded in obtaining a license directly from Boots and, after lengthy FDA proceedings, obtained approval to market an OTC product which it began distributing under the trademark Advil in 1983.

McNeil sought a license from Upjohn but these negotiations failed and Upjohn instead licensed Bristol-Myers, which now markets an OTC ibuprofen product under the trademark Nuprin. Having initially failed to obtain the right to market its own ibuprofen product and fearing that competition from ibuprofen would seriously erode its market for Tylenol, beginning in September 1983 McNeil repeatedly intervened before the FDA in opposition to AHP's NDA for ibuprofen. McNeil unsuccessfully sought to persuade the FDA to send AHP's application back to the FDA's Arthritis ***574** Advisory Committee, pointing to adverse reports on the side effects on the central nervous system ("CNS") of prescription-level use of ibuprofen (up to 800 mg. per dose and 3200 mg. per day).

AHP sought to obtain FDA approval for OTC dosages of ibuprofen up to 1600 mg. per day (one-half the prescription daily maximum), but the FTC finally ruled that the OTC package instructions should specify a dosage of one or, if necessary, two 200 mg. tablets, with no more than six tablets, or 1200 mg., in any 24–hour period.

McNeil repeatedly filed with the FDA lengthy petitions and met with FDA officials in an effort to persuade the FDA to eliminate the statement in the FDA's Summary Basis of Approval ("SBA") of OTC ibuprofen that

> [c]onsumers taking ibuprofen at recommended doses will experience comparable 'common side effects' to those they experience with available OTC analgesics, i.e., acetaminophen and aspirin if the latter 2 drugs are taken at regular strength doses [325–650 mg.]. At 'extra strength' doses [1000 mg.] the incidence of adverse side effects to aspirin and acetaminophen would be expected to be higher.

McNeil's efforts were to no avail; and in May 1984 the SBA for OTC ibuprofen was issued by the FDA with these findings, along with others to the effect that the incidence of gastrointestinal problems incurred in the use of ibuprofen was significantly lower than with aspirin and that ibuprofen was less dangerous when taken in overdose than either aspirin or acetaminophen.

McNeil also unsuccessfully sought to convince the FDA to rule that the packages of OTC ibuprofen should bear a warning of the possibility of gastric ulcers and renal dysfunction.

Whether McNeil was motivated in part by a public-spirited desire to protect consumers can be judged by the fact that McNeil continued its plan to market its own OTC ibuprofen product after expiration of the Boots U.S. patent in 1985. It recently introduced such a product under the trademark Medipren. In its confidential NDA for Medipren, filed in September 1984, McNeil praised ibuprofen's safety record even at the higher prescription dosage levels and emphasized its substantial advantages over aspirin. This was only a few months after McNeil had vainly sought to win restrictions on the FDA's approval of OTC ibuprofen, and at the very time McNeil was publishing the challenged advertisements unfavorably comparing ibuprofen with acetaminophen and in some respects even with aspirin.

Having failed to protect its market for Tylenol by erecting barriers in the FDA, McNeil counterattacked in the marketplace against the ibuprofen invasion. It engaged in a massive program of "sampling" (sending to physician free samples for distribution to patients) and "couponing" (distributing coupons for purchases at discount prices) as well as a near saturation-level advertising campaign. It is this advertising campaign which triggered AHP's complaint in this action.

The Checklist

[1] Perhaps the principal target of AHP's charge of false advertising by defendants is a four-page colored folder which was widely distributed to physicians, both by mail and during detailing visits by AHP's sales representatives or "detail men." The focus of AHP's complaint is the third page of the folder, on which appears a table entitled "Comparison of Non-Rx Analgesic Safety Profiles."

In the table there are four vertical columns, the left-hand column being headed "Potential side effects at recommended doses." Beneath this heading are listed seventeen side effects, the first ten being grouped under a subheading "minor side effects" and the last seven under "serious side effects." The other three vertical columns are respectively headed "Plain/buffered Aspirin,"

"Ibuprofen" and "Extra-Strength Tylenol." Opposite each of the seventeen listed side effects, the columns for the respective analgesics contain either a check mark, an asterisk or a blank space. ***575** In much smaller print at the bottom of the page, there are footnotes signifying that a check mark "Indicates occurrence only. Incidence may vary" and that an asterisk means "Relatively rare for this effect."

In the "aspirin" column, there are check marks opposite thirteen of the seventeen listed side effects and asterisks opposite the other four. In the ibuprofen column there are check marks opposite sixteen of the seventeen and a blank space opposite the other ("delaying ulcer healing"). In the Extra-Strength Tylenol column, there is a check mark opposite only one ("stomach upset"), asterisks opposite six and blank spaces opposite ten.

The fourth page of the folder summarizes the claims of the checklist on the preceding page. It is headed "Superior non-Rx analgesia." Below this in large letters are the words "Extra-Strength Tylenol" and below that there are two items, the second of which reads "Safety profile superior to both aspirin and ibuprofen."

On both pages 3 and 4 there are footnotes citing a total of eight technical publications in purported support of the representations as to the adverse side effects of the respective analgesics.

AHP does not deny that ibuprofen produces, in at least a small percentage of users, each of the side effects opposite which check marks appear in the ibuprofen column on the checklist. What it does complain of is the unfavorable comparison with acetaminophen and especially with aspirin. It strenuously urges that ibuprofen is as good or better than acetaminophen in the respect of freedom from most of the listed side effects and better than aspirin with respect to all of them.

Defendants argue that AHP has studiously ignored the import of the footnote definition of a check mark as indicating only occurrence and not incidence. Defendants support that argument by pointing to the common use of similar checklists in the medical literature, for example, in the United States Pharmacopeia ("USP") to indicate drug-drug interactions and contraindications for use. However, it is interesting to note that in the USP tables of side effects, check marks are not used to indicate occurrence without regard to incidence. Instead, the USP uses code letters to indicate incidence: M for more frequent (3–9%), L for less frequent (1–3%); R for rare (less than 1%); and U for Unknown.

Moreover, McNeil's use of much smaller type for the footnotes increases the likelihood that readers may overlook them. But, much more significantly, the central message of the checklist is its comparison among the three analgesics. For example, if opposite a particular side effect there is a check mark in the ibuprofen column and only an asterisk in the aspirin column, there is a clear representation that aspirin is superior to ibuprofen in the respect of freedom from that side effect. If in fact ibuprofen is not significantly inferior to aspirin in that respect, the representation is false. It is no defense that ibuprofen does cause that side effect in some users, so that the use of a check mark in the ibuprofen column is technically correct in light of the footnote explanation of the meaning of the check mark. That does not cure the falsity of the comparison between drugs.

AHP also complains of the subliminal message that the checklist conveys by using a heavier line to separate the Tylenol column from the aspirin and ibuprofen columns than is used to separate the latter two columns. AHP urges that this visual "lumping" or "linking" of ibuprofen with aspirin tends to reinforce the false impression of equivalency of their safety profiles. Such an impression was indeed a stated objective of McNeil's advertising campaign, particularly the advertisements directed at physicians and health professionals. As McNeil's Vice President Chandler Simonds stated in an internal memorandum outlining the objectives of the campaign:

> Professionally, we will concentrate on clearly defining the safety advantages of Tylenol to the medical community, lumping the side effect profile to that of aspirin.

***576** John Wernette, McNeil's Product Manager for Tylenol Professional Marketing stated in another internal memorandum that the campaign objective was to

> accomplish OTC ibuprofen's unsafe positioning by linking its side effects profile to that of aspirin.

Central nervous system ("CNS") effects

The checklist includes five potential CNS side effects: dizziness, nervousness, tinnitus, headache and drowsiness. In the ibuprofen column, there are check marks opposite all five of these side effects; in the aspirin column, there is a check mark opposite only one of the five, tinnitus (ringing in the ears), and asterisks opposite the remaining four; in the Extra-Strength Tylenol column, there are asterisks opposite the same four, and a blank opposite tinnitus. The use of an asterisk to characterize the occurrence of four of the CNS side effects as "relatively rare" in the case of aspirin and Extra-Strength Tylenol while check marks are used for ibuprofen gives the unmistakeable impression that ibuprofen is significantly worse than both aspirin and Tylenol in the causation of CNS side effects.

McNeil called no trial witness and offered no deposition testimony to support its claim that ibuprofen at OTC doses causes these side effects in a significant number of users. Instead, it relies upon the Physician's Desk Reference ("PDR"), the USP and similar references, which indicate that ibuprofen *at prescription dosage levels* has been associated with the claimed CNS side effects in a small percentage of users. However, McNeil's designated CNS expert, Dr. Andrei Calin, admitted in his deposition that he knew of no basis for distinguishing ibuprofen and acetaminophen *at OTC levels* with respect to the incidence of CNS effects.

That is perhaps not surprising in view of AHP's introduction at the trial of thirteen studies on the CNS side effects of ibuprofen (400 mg.) and acetaminophen (1000 mg.) in double-blind tests against a placebo control. Seven of these studies were sponsored by McNeil itself and six by AHP. Both the McNeil studies and the AHP studies, considered overall, tend to show that ibuprofen is somewhat *better* than acetaminophen in the respect of freedom from the CNS effects referred to in the checklist, and even slightly better than the placebo! McNeil's efforts to discredit these studies, including its own, were not convincing.

McNeil did not even attempt to furnish any support for its representation that OTC ibuprofen produces CNS effects more frequently than aspirin, perhaps the unkindest cut of all those in the checklist.

On the basis of the evidence submitted, the Court finds that the difference between the incidence of CNS side effects caused by ibuprofen and acetaminophen is not statistically significant and that insofar as the checklist indicates otherwise, it is false.

Gastrointestinal effects

The checklist includes three gastrointestinal side effects which are classified as "minor" (stomach upset, mucosal irritation and/or erosion and occult bleeding) and four classified as "major" (causing/activating gastric ulcers, activating duodenal ulcers, delaying ulcer healing and massive GI hemorrhage). In the aspirin column there are check marks opposite all seven of these side effects; in the ibuprofen column there are check marks opposite all but one (delaying ulcer healing); and in the Extra-Strength Tylenol column there is a check mark opposite only one (stomach upset) and blank spaces opposite all the others.

The evidence indisputably establishes that ibuprofen does indeed cause every one of the indicated gastrointestinal side effects in at least a minor percentage of users. It is equally clear that in every one of these respects it is markedly superior to aspirin and significantly inferior to acetaminophen. The FDA, after a review of all the available literature, concluded that "the risk of serious gastrointestinal damage is less with ibuprofen than with aspirin" but that "ibuprofen has been associated with gastrointestinal ulceration and hemorrhage." And in its own NDA for ibuprofen, McNeil told the FDA that "ibuprofen ***577** in equipotent doses has between one-fifth to one-half the gastric irritant capacity of aspirin." and "causes fewer and less severe gastric mucosal lesions."

Thus there is no question that it would have been appropriate to represent in the checklist that ibuprofen tends to cause the listed gastrointestinal side effects; the only dispute concerns whether it was misleading to use identical marks for ibuprofen and aspirin and risk creating the misimpression that the two are equivalent in the indicated respects.

The court concludes that it was, for a combination of reasons. First, McNeil's choice of check marks rather than a more precise indication, such as the letter code used in the USP, was surely influenced by McNeil's objective

of equating the safety profiles of aspirin and ibuprofen; second, the fact that the explanatory footnotes are in much smaller type than the remainder of the checklist creates at least some hazard that even health professionals who read the checklist casually will not understand that a check mark indicates "occurrence only" and not incidence. Third, the fact that asterisks are available to designate side effects which are "relatively rare" informs more thoughtful readers that each of the indicated side effects occurs too frequently in ibuprofen users to be called "relatively rare." Some might even get the impression that "relatively" refers to aspirin and that the failure to use asterisks for ibuprofen means that the incidence of the side effects with ibuprofen use is no rarer than it is with aspirin. Finally, the grouping of aspirin and ibuprofen at one side of a heavier vertical line with Extra-Strength Tylenol alone on the other side tends to induce readers to perceive the two NSAIDs as members of a group sharing common properties and disadvantages, which is precisely the effect McNeil intended.

It is true that aspirin and ibuprofen have similar mechanisms of action and tend to cause the same types of side effects, but it is unfair to create the impression the risks of using ibuprofen are comparable to those involved in using aspirin, as McNeil has done.

Hemostatic effect

The checklist includes one item relating to hemostasis generally (as distinguished from occult or gastrointestinal bleeding), namely, "prolonged bleeding time."

AHP does not contend that ibuprofen does not prolong bleeding time. Indeed, the evidence indisputably establishes that ibuprofen shares with the other NSAIDs the characteristic of inhibiting the synthesis of prostaglandins which enhance platelet aggregation and promote blood clotting.

Both the PDR for Motrin and the USP report this effect, and AHP's own expert, Dr. Sigmund Kahn, confirmed it, even at OTC dosage levels. Moreover, in its SBA for OTC ibuprofen, the FDA stated that one of its pharmacologic effects is "inhibition of collagen-induced platelet aggregation."

AHP instead urges that ibuprofen does not prolong bleeding time significantly more than Extra-Strength Tylenol and that either there should be check marks in both the ibuprofen and Extra-Strength Tylenol columns or in neither of them. The evidence does not support AHP's position that acetaminophen and ibuprofen are comparable in their antihemostatic effects.

The Court therefore finds no error in the checklist insofar as concerns prolongation of bleeding time.

Allergic Reactions

Among the "Serious Side Effects" included in the checklist are "Allergic reactions (asthma attacks, wheezing, dyspnea, rhinitis, urticaria, angioneurotic edema, anaphylactic shock)." Opposite this item there are check marks in the aspirin and ibuprofen columns but only an asterisk in the Extra-Strength Tylenol column.

AHP concedes that it is "technically true" that allergic reactions occur more frequently with aspirin and ibuprofen than with acetaminophen, but contends that the checklist exaggerates the difference, which exists only with respect to less than 1% of the general population who are sensitive to ***578** aspirin. McNeil disputes AHP's contention as to the number of persons susceptible to allergic reaction, asserting that at least 4.5 million Americans are at risk. The Court finds that McNeil's position is better supported than that of AHP, the evidence reflecting that 10–20% of the 9 million asthmatics are aspirin-allergic, as well as 20–30% of those suffering from chronic urticari (hives), a condition suffered by up to 20% of the population at some time during their lives.

Significantly, the FDA requires that the Advil be sold with a warning: "Do not take this product if you have had a severe allergic reaction to aspirin; e.g.—asthma, swelling, shock or hives...." By contrast, the FDA has approved an Extra-Strength Tylenol label stating that it is "not likely to cause a reaction in those who are allergic to aspirin and [is] especially well suited for such persons." And, most revealingly, on the label of its own acetaminophen product, Anacin–3, AHP emphasizes its safety for use by aspirin-sensitive persons.

The Court accordingly finds that, insofar as allergic reaction claims are concerned, the checklist is correct.

Renal dysfunction

Another of the "serious side effects" included in the checklist is "renal dysfunction." Opposite this item in the

aspirin and ibuprofen columns are check marks, while there is an asterisk in the Extra-Strength Tylenol column.

AHP concedes that ibuprofen can cause renal failure in a small percentage of users who have a predisposing kidney condition, but contends that it is no more likely than acetaminophen to cause kidney damage. AHP relies in part on the SBA for Advil, but the FDA stopped short of finding the two drugs equivalent in their renal effects:

> [I]buprofen shares with other NSAIDs the potential for adverse effects on renal function through its inhibitory effect on the synthesis of vasodilatory prostaglandins. In normal individuals the effects are unimportant. In patients with pre-existing renal disease, cirrhosis, heart failure, hypertension, lupus erythematosis, burns and sepsis, however, signs and symptoms of renal failure may appear acutely. This is functional, not anatomical, and is reversible when the nonsteroidal is stopped. Patients with the conditions listed should, however, use ibuprofen (also aspirin and acetaminophen) only after discussion with, or under the supervision of, a physician.

Saying that acetaminophen should not be taken by certain classes of persons at risk without consulting a physician is not the same as saying that the hazard of renal failure in such persons when acetaminophen is taken is equal to that involved in the use of ibuprofen.

AHP also relies on the testimony of its expert nephrologist, Dr. Michael Dunn. But Dr. Dunn conceded that ibuprofen poses a threat of kidney damage to more persons than acetaminophen, characterizing it, along with other NSAIDs, as a "prototypical offending agent" for adverse renal reactions.

There are serious questions, however, whether the incidence of renal dysfunction associated with ibuprofen use is so slight that the use of a check mark rather than an asterisk is misleading, and whether the failure to use even an asterisk for acetaminophen overstates the difference between the two drugs. The Court finds that the message thereby conveyed is misleading.

Acetaminophen is not free from the possibility of serious kidney damage. Directly following the above-quoted statement in the SBA for Advil, the FDA noted:

> OTC analgesics have been associated with so called "analgesic nephropathy (also called "analgesic abuse syndrome"). In some countries this syndrome is responsible for a significant fraction of end stage renal disease. At one time the papillary necrosis and chronic interstitial nephritis with secondary glomerular changes associated with this syndrome were thought to be associated only with phenacetin (which, because of this danger, was removed from analgesics in the U.S. and a number of other countries). ***579** Currently, however, it is thought the syndrome is associated with combination analgesic preparations taken in maximum doses over long periods. These combination analgesic products generally contain acetaminophen, the major metabolite of phenacetin, in addition to aspirin. Although ibuprofen has not been implicated in this condition, it (like other nonsteroidols and acetaminophen) does cause papillary necrosis in animals.

Although Dr. Dunn conceded that more persons are at risk with ibuprofen, he testified that renal problems, when they do occur, are more severe with acetaminophen, so that overall the two drugs are roughly equal in the respect of renal hazard. However, as McNeil's expert toxicologist, Dr. Lawrence Prescott, explained, most of the technical articles reporting renal failure following acetaminophen use involved chronic alcoholics, many of whom had apparently taken massive overdoses, although, with understandable unreliability, they may have reported only normal therapeutic dosage.

The Court finds that, to be accurate, the checklist should have indicated by an asterisk that acetaminophen causes renal dysfunction at least with "relatively rare" incidence. If this had been done, it might not have been misleading to indicate by a check mark that the risk of renal dysfunction involved in the use of ibuprofen was somewhat greater. But to indicate that acetaminophen does not cause renal dysfunction at all, while the risk of using ibuprofen is two categories greater—too substantial to be classified as "relatively rare"—is impermissibly misleading.

Drug-drug interactions

Under "serious side effects" the checklist includes "drug-drug interactions." There are check marks opposite this item in the aspirin and ibuprofen columns but only an asterisk in the Extra-Strength Tylenol column.

AHP contends that this is misleading because ibuprofen and acetaminophen are equally prone to cause adverse reactions when taken in conjunction with other drugs. AHP's pharmacological expert, Dr. Louis Lasagna, so testified, but his generalized conclusion was not supported by the technical literature, except insofar as alcohol is considered a drug (the risk to chronic alcoholics of acetaminophen use being well documented).

As McNeil's pharmacy expert, Dr. Daniel Hussar, testified, the literature copiously reports adverse interactions between ibuprofen and diuretics, anti-hypertensives, anti-coagulants, lithium, corticosteroids, and barbiturates, as well as alcohol. Indeed, all of these interactions are confirmed by the USP.

AHP submitted no persuasive evidence that acetaminophen is comparably susceptible to drug-drug interactions. The Court accordingly finds that this aspect of the checklist is correct.

Hepatic effects

[2] AHP contends that it was misleading to compare the safety profiles of the OTC analgesic without including, as one of the side effects compared, potential liver damage, and without mentioning that acetaminophen is more dangerous when taken in substantial overdoses.

The evidence, including McNeil's own studies, clearly establishes that acetaminophen can cause liver damage, particularly when taken at higher dosage levels by chronic alcoholics and others having pre-existing liver damage, or when taken at massive overdose levels even by persons with no history of liver trouble. There is no evidence of a comparable risk in the use of ibuprofen.

McNeil does not seriously dispute that, if hepatic effects were included in the checklist, ibuprofen would have to be shown as superior to acetaminophen. Instead, it merely contends that the checklist was designed to promote the sale of Extra-Strength Tylenol and that the law does not require that they disclose the disadvantages of the product as well as its advantages. As McNeil sums up this argument, the Lanham Act is not a full disclosure law, like the securities acts.

***580** In the usual type of consumer advertising, McNeil's argument is probably valid. If an automobile manufacturer's advertisement presents a table listing all of the features which its automobile includes as standard equipment and which the competition includes only as an extra-cost option, no one really regards the advertisement as unethical because the list of features does not also include those which the competition provides as standard and the advertiser does not.

But where an advertisement is captioned "Comparison of Non-Rx Analgesic Safety Profiles," the reader might well be led to believe that the "profile" has not been pruned to favor the advertiser, but is complete—at least to the extent of including all of the side-effects as to which there is a significant difference between OTC analgesics. This impression is reinforced by the statement on the following page of the folder to the effect that Extra-Strength Tylenol has a "Safety Profile superior to both aspirin and ibuprofen."

Where the health of consumers is at risk, advertisers must be held to a higher standard of commercial ethics. The Court finds that the checklist's omission of hepatic side effects and overdose hazard from the safety profiles for the admitted purpose of concealing disadvantages of acetaminophen which might diminish sales of Extra-Strength Tylenol, creates an unacceptable potential for misleading even the professional audience at which it was directed.

Superior safety profile claim

[3] AHP also complains of McNeil's claim on page four of the folder that Extra-Strength Tylenol has a "Safety profile superior to both aspirin and ibuprofen."

As detailed above, the evidence tends to show that acetaminophen is somewhat superior to ibuprofen (and even more superior to aspirin) in the respect of causing certain adverse side effects, while there is no significant difference between them with respect to other side effects (and ibuprofen is somewhat superior to acetaminophen with respect to still others not mentioned in the folder).

The Court therefore finds that McNeil's claim of a superior safety profile is either true or at least within the tolerable range of commercial puffery. The consuming public is conditioned to view such generalized comparisons with healthy skepticism, and medical professionals are not likely any more susceptible to being misled by promotional materials directed at them.

The "Rotten Apple" Advertisement

Another print advertisement about which AHP passionately complains is the so-called "rotten apple ad" which appeared in a number of medical journals from July to October of 1985, when it was voluntarily withdrawn by McNeil after a spate of complaints that it was in poor taste.

It prominently features a large full-color photograph of an apple which appears attractive until you notice what appears to be a worm hole surrounded by a darkened, apparently rotten area. Above the apple is the caption "Aspirin and Ibuprofen—The Closer You Look ..." The text below continues

> the clearer your first Choice in Non-Rx Analgesia: Extra-Strength Tylenol Acetaminophen. Both aspirin and ibuprofen can cause unpredictable gastrointestinal irritation and potentially severe allergic reactions:
>
> • Up to # of newly diagnosed gastric ulcers may be related to aspirin therapy.
>
> • Patients may be asymptomatic yet show ulcer craters.
>
> • Buffering aspirin is ineffective in reducing GI irritation.
>
> • Higher incidence of potentially serious allergic reactions exists with aspirin and ibuprofen therapy.

The first and third of the bulleted items specifically refer only to aspirin. Only the fourth item expressly mentions ibuprofen. As discussed above, the claim in this item that aspirin and ibuprofen can cause allergic reactions is literally true. Nevertheless, AHP contends that the "rotten apple ad" gives the false impression that aspirin ***581** and ibuprofen are equivalent in their gastrointestinal and allergenic effects and that both are inferior in these respects to acetaminophen, making them the "rotten apples" in the OTC analgesic fruit bowl.

To support this contention, AHP conducted a survey of physicians who were asked to read the advertisement and then put it aside and answer a series of questions. At the trial, the appropriateness and fairness of most of the questions were challenged either by expert witnesses or by the Court itself and in some instances AHP's survey expert effectively conceded their unsuitability. In its post-trial briefs, AHP has relied on the answers to only one multiple-choice question, No. 14, which reads as follows (the percentage of respondents selecting each of the choices is indicated):

> *Question 14* : Please read each of the statements on this card carefully and tell me which one best describes what the ad communicates to you.
>
> When taken at non-prescription dosage levels:

1.	Aspirin and ibuprofen have the same likelihood of causing gastric ulcers	7%
2.	Aspirin and ibuprofen have about the same likelihood of causing gastric ulcers	39%
3.	Aspirin and ibuprofen have a somewhat different likelihood of causing gastric ulcers	3%

4.	Aspirin and ibuprofen have a very different likelihood of causing gastric ulcers	1%
5.	None of the above; the ad does not communicate to me any of the above degrees of similarity or dissimilarity	2%

Thus, as AHP points out, a total of 46% of the physicians in the survey responded that the advertisement communicated to them the message that the likelihood of gastric ulcers resulting from aspirin and from ibuprofen is either "the same" or "about the same."

McNeil attacks the survey as unreliable for several reasons. First, McNeil urges that the survey results were influenced by the fact that Question 14 was in "closed-end" or multiple-choice form, rather than in open-ended form—i.e., merely asking the respondents to state in their own words the message they received from the advertisement. It is well recognized that closed-end or multiple-choice questions are inherently suggestive and invite guessing by those who did not get any clear message at all. AHP responds that for this reason Question 14 was "filtered" by first asking each respondent, in Question 12, whether he took away any message about similarity or dissimilarity of the tendencies of aspirin and OTC ibuprofen to cause gastric ulcers. 47% of the doctors answered that they got no such message from the advertisement. They were "screened out" and only the remaining 56%, who said that they did, were asked to answer Question 14 by choosing the statement that best described that message.

However, AHP's own survey expert stated that even where a closed-end question is properly filtered, the "background" or "noise level" is 20%—meaning that any percentage response below that level is statistically insignificant and unreliable.

But the most serious shortcoming of Question 14 is that its list of choices is incomplete, inexplicably omitting to include, as one of its options, the literal meaning of the advertisement! Thus the only positive choices which the respondents were given are all literally false. While they were given the option of indicating that none of the positive statements is correct, there is a natural tendency to select one of the positive responses. To be fair, the list of choices should have included at least one statement which is literally correct, such as:

> Both aspirin and ibuprofen can cause gastric irritation, but the advertisement does not compare the likelihood that ibuprofen might cause such effects with the likelihood that aspirin might do so.

Moreover, the list of choices was seriously slanted in another way: among the four positive choices, the latter two were so obviously false that they could almost as ***582** well have been omitted. Clearly the advertisement did not say anything about a *difference* between the likelihood that aspirin might cause gastric ulcers and the likelihood that ibuprofen might do so. Giving the respondent an opportunity to choose either a statement that aspirin and ibuprofen have a "somewhat different" likelihood of causing stomach ulcers and a statement that they have a "very different" likelihood of doing so creates only the illusion of additional choices. No one who has read the advertisement with even a grade school level of comprehension is likely to select either of those options. That undoubtedly explains why a total of only 4% of the respondents did so, while the others were effectively steered to one of the first two choices. What percentage would have selected the literally correct statement set forth above, if it had been included as a positive choice, we can

only guess. But it seems certain that it would have been much higher than the total of 6% who selected one of third, fourth and fifth choices actually presented.

Finally, it should be noted that Question 14 implies that the "rotten apple ad" contains a representation that ibuprofen can cause gastric ulcers. A review of the advertisement will confirm that it contains no specific statement that ibuprofen causes gastric ulcers *at all,* much less any statement as to the likelihood of such effect.

Ibuprofen *can* cause gastric ulcers, but the "rotten apple ad" does not expressly say so. It says that "aspirin and ibuprofen can cause unpredictable gastrointestinal irritation," but that is the only specific linkage between ibuprofen and gastrointestinal problems. The first two bulleted items concern gastric ulcers, but the first mentions aspirin alone and the second names neither aspirin nor ibuprofen. Indeed, the second merely makes a general statement, well supported by the evidence and not disputed, to the effect that a person can have gastric ulcers without knowing it.

But a doctor reading Question 14 without the advertisement to check against, could well be misled into believing that it must have specifically stated that ibuprofen can cause gastric ulcers. Otherwise, why would Question 14 ask how the advertisement compared the likelihood that ibuprofen might cause ulcers to the likelihood that aspirin might do so.

McNeil sponsored its own survey of physicians as to the message they received from the "rotten apple ad." It was just as bad as the AHP survey. The doctors were asked a multiple-choice question in which they were directed to choose between three statements to the effect that the frequency of gastrointestinal irritation for aspirin and ibuprofen are "the same," "different" or "neither." The first two choices were just as obviously false and therefore illusory as the last three choices in Question 14 of the AHP survey.

The advertisement clearly did not say that the risk of the specified side effects was the "same"—i.e., precisely identical—for the two drugs. And it even more obviously did not state that it was "different." Thus all of the respondents were steered inexorably to the only remaining choice, which was "neither" of the first two. It would obviously have been much fairer to give the respondents an intermediate option which stated that aspirin and ibuprofen were "similar" in their side effects, instead of giving as positive choices only the two improbable extremes.

The difference in bias between the two surveys is dramatically shown by the fact that only 2% of the respondents in the AHP survey chose the catch-all option that the advertisement does not communicate any of the specified degrees of similarity, while in the McNeil survey 52% of the respondents did so. It is difficult to believe that it was a mere coincidence that when each party retained a supposedly independent and objective survey organization, it ended up with survey questions which were virtually certain to produce the particular results it sought. This strongly suggests that those who drafted the survey questions were more likely knaves than fools. If they were indeed the former, they must have assumed that judges are the latter.

***583** **[4]** Obviously it would be preferable for litigants who wish to conduct surveys to submit the proposed questions for *inter partes* challenge and court approval before incurring the substantial expense of conducting interviews which might produce only useless results. In any event, the Court can place little or no reliance on these survey results and is unfortunately left to decide, largely on the basis of the advertisement itself, what message it conveyed to the professional readership at which it was directed.

[5] The Court finds that, although every statement in the "rotten apple ad" is literally correct, it unfairly creates the impression that ibuprofen and aspirin are comparable in their gastrointestinal and allergenic effects. The headline "Aspirin and Ibuprofen—The Closer You Look ..." links both indiscriminately to the rotten apple picture below. The text begins with a general statement which continues the linkage: "Both aspirin and ibuprofen can cause unpredictable gastrointestinal irritation and potentially severe allergic reactions:" This general statement is immediately followed by the four bulleted items which are given as supporting examples. The fact that only one of the four bulleted items specifically refers to ibuprofen tends to be overlooked since all four items are presented in support of a statement concerning the side effects of both aspirin and ibuprofen.

In its main post-trial memorandum, AHP asserts that the technical publications which are cited in the footnotes in ostensible support of the claims in the advertisement merely report on the adverse side effects of aspirin and do not even mention ibuprofen. That is true with respect to the three articles cited in support of the first three bulleted items but, as already noted, none of those items specifically mentions ibuprofen. Of the two articles cited in support of the fourth item, the only one in evidence (DX SO) does state that ibuprofen induces adverse reactions in asthmatic patients.

McNeil's Consumer Advertising

AHP challenges a series of Tylenol print advertisements and television commercials which were widely published or broadcast with mind-numbing frequency and which claim (1) that OTC ibuprofen causes more stomach upset than Tylenol; (2) that there is no more potent OTC pain reliever than Extra-Strength Tylenol; and (3) that hospitals trust Tylenol and use or recommend it much more frequently than other OTC pain relievers, including ibuprofen. McNeil insists that all of the statements it made in these advertisements and commercials are true.

Stomach upset claims

[6] A Tylenol print advertisement which AHP refers to as "representative" states:

> Extra-Strength Tylenol gives you unsurpassed pain relief without the stomach irritation you can get with aspirin or the ibuprofen pain relievers.

AHP argues that "stomach irritation" is synonymous with "stomach upset," which refers to *subjective* gastrointestinal symptoms of physical discomfort, such as dyspepsia, nausea, flatulence, heartburn and diarrhea. Based on this definition, AHP argues that the only reliable measure of the incidence of such side effects is a clinical trial in which patients are successively given the medications in question, as well as a placebo, and report on any manifestation of these symptoms.

AHP relies in particular on a group of clinical trials whose collective results are reported at page 18 of the SBA for Advil. Insofar as stomach irritation is concerned, that reliance is misplaced. The clinical results reported by the FDA lumped together *all* side effects occurring at a 1% incidence level and above; there was no separate reporting of the incidence of stomach irritation. The "most commonly involved" symptoms included CNS effects such as "drowsiness * * * dizziness * * * blurring of vision, fatigue, weakness, woozy feeling and numb feelings."

As AHP well knows, but did not discuss in this connection, the SBA which it cited ***584** includes a separate section reporting specifically on "Gastrointestinal tract reactions." As previously noted, in that section the FDA stated that it is "generally recognized that nonsteroidal anti-inflammatory drugs may produce gastrointestinal intolerance ranging from mild dyspepsia to overt bleeding." Although it was added that "the risk of serious gastrointestinal damage is less with ibuprofen than with aspirin as are gastrointestinal hemorrhage and occult blood loss," the FDA concluded:

> Nevertheless, ibuprofen has been associated with gastrointestinal ulceration and hemorrhage; it should not be used by individuals with a known ulcer or previous bleeding * * * except after discussion with or under the supervision of a physician.

AHP also relies on the aforementioned series of double-blind placebo-controlled clinical tests, some sponsored by McNeil and some by AHP, in which the patients reported, *inter alia,* on any adverse gastrointestinal symptoms. Overall, a slightly smaller percentage of those given ibuprofen reported stomach upset than those given acetaminophen, although the difference was too slight to be considered statistically significant. However, both percentages were substantially higher than with the placebo.

Thus, insofar as concerns *subjective* gastrointestinal symptoms, sensible to the patient, in OTC dosages, ibuprofen is at least as safe as acetaminophen. But the evidence establishes that in terms of *objective* gastrointestinal side effects, such as ulceration, hemorrhage and occult bleeding, acetaminophen poses

a significantly lower risk than ibuprofen, even though ibuprofen is markedly superior to aspirin.

The term "stomach irritation," as used in McNeil's consumer advertising, is broad enough to include both subjective and objective side effects. The Court is not persuaded by AHP's attempt to equate that term with "stomach upset" and thereby limit it to symptoms perceptible to the user.

The Court therefore finds that, insofar as the challenged advertisements claim that Tylenol causes less stomach irritation than aspirin or ibuprofen, they are literally true. The only question is whether they unfairly suggest that ibuprofen causes as much stomach irritation as aspirin.

Neither party submitted the results of any consumer surveys respecting the impressions created by these advertisements, which, considering the quality of the physician surveys discussed above, may be just as well. And the Court, being a medically unsophisticated consumer of OTC analgesics, is probably better equipped to judge the effect of the consumer advertising on its audience than it is to divine what physicians might think about the advertisements directed at them.

The Court finds that McNeil's consumer advertising does not unfairly give consumers the impression that ibuprofen is as likely to cause stomach irritation as aspirin is, with the sole exception of the advertisement quoted above, which is far from being "representative," as AHP termed it.

[7] That advertisement might mislead readers because it refers to "*the* stomach irritation you can get with aspirin or the ibuprofen pain relievers" (emphasis added). The use of the definite article "the" tends to give the impression that you get the *same* stomach irritation with either aspirin or ibuprofen.

[8] The other advertisements do not share this tendency. Many of the earlier McNeil commercials stated that Tylenol can give "effective relief without the stomach irritation possible with aspirin or any other pain reliever." Ibuprofen was not identified, and the reader was not likely to get the impression that *all* other pain relievers produce the same degree of stomach irritation. The typical consumer was not likely to know that there were only three basic types of pain relievers available OTC; indeed the reference to "any other pain reliever" suggests that there was more than one such "other."

The most recent commercials have stated that "Tylenol doesn't irritate your stomach the way aspirin or even ibuprofen can." ***585** The word "even" clearly draws a distinction between aspirin and ibuprofen; the unmistakable implication is that ibuprofen causes significantly less stomach irritation than aspirin. It is like saying that acetaminophen is superior to aspirin and, *mirabile dictu,* even superior to ibuprofen.

Efficacy claims

[9] In countless print advertisements and television commercials, McNeil has repeated with wearying persistence what has virtually come to be its theme song:

> Extra-Strength Tylenol. You can't buy a more potent pain reliever without a prescription.

AHP charges that this claim is false—that Advil is a more effective pain reliever than Extra-Strength Tylenol. McNeil freely admits that Extra-Strength Tylenol is not a more effective pain reliever than OTC ibuprofen, but insists that Tylenol is fully *as* effective, so that the claim in question is true.

AHP relies on a series of seven double-blind, placebo-controlled clinical studies in which patients reported on the relief they obtained from different types of pain after taking acetaminophen (1,000 mg.), ibuprofen (400 mg.) or placebo. McNeil challenges these studies on various grounds and relies on its own study involving a much larger group of patients suffering from headache pain.

The clash between the parties over the reliability of these studies was a fascinating if mind boggling journey through the *terra incognita* of medical statistics and epidemiology, involving disputes over the suitability of such pain models as episiotomy and third molar extractions, the propriety of various measures of pain relief (total pain relief or TOTPAR, maximum pain relief or MAXPAR, sum of the pain intensity differences or SPID, maximum pain intensity difference or MAXPID, or the overall evaluation, GLOBAL), and which test of statistical significance (Scheffe, Duncan, two-tailed t or one-tailed t) should be used.

A detailed analysis here of these issues would be an unwarranted imposition on both the writer and the reader. Suffice it merely to say that, after considering all of the evidence, the Court finds that in the treatment of mild to moderate pain such as headache, there is no significant difference in effectiveness between Extra-Strength Tylenol (1000 mg.) and Advil (400 mg). In the treatment of severe pain, Advil is substantially more effective, as it is in relieving inflammation.

Thus, McNeil's claim that "You can't buy a more potent pain reliever without a prescription" is simply not true. Most laymen, knowing the foregoing facts, would surely regard Advil as "more potent."

It would be accurate to state instead that, "*for mild to moderate pain,* you can't buy a more *effective* pain reliever without a prescription." For this level of pain, Advil's added potency affords no increased relief to justify the increased hazard of certain types of side effects.

It should perhaps be noted in passing that the Court was not persuaded by McNeil's argument that, in comparing the effectiveness of the two drugs, a dose of two tablets of Extra-Strength Tylenol (1000 mg.) should be compared with one tablet of Advil (200 mg.), because these are the dosages recommended by their respective package instructions. To the contrary, the FDA-approved instructions for Advil read:

> Take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used, but do not exceed 6 tablets in 24 hours, unless directed by a doctor. The smallest effective dose should be used.

Thus, as McNeil conceded and the Court found in *McNeilab, Inc. v. Bristol-Myers Co.,* —— F.Supp. ——, No. 86–4163 (E.D.Pa. Sept. 5, 1986), 400 mg. is *an* authorized dose of Advil—one that may be bought and used without a prescription and within the approved dosage instructions. Therefore, unless 1000 mg. of Tylenol is as potent as 400 mg. of Advil (which it is *not* against severe pain), McNeil's claim that "you can't buy a more potent pain reliever without a prescription" is inaccurate, even though the Advil package instructions recommend taking ***586** 400 mg. only if 200 mg. fails to give the desired relief.

"Hospitals trust" claims

[10] In McNeil's most aggressively pursued and costliest television campaign, an announcer, usually an attractive woman, after such introductory remarks as "I want a pain reliever I can really trust," or "I sometimes wonder how mothers know what to give their family," makes a statement along the following lines:

> "When I sprained my ankle and went to the hospital, they gave me Tylenol.
>
> "I learned that Tylenol is the pain reliever hospitals use most.
>
> "Hospitals trust Tylenol.
>
> "Last year, hospitals dispensed ten times as much Tylenol as the next four brands combined.
>
> "If hospitals trust Tylenol, shouldn't your choice be Tylenol?"

AHP attacks this so-called "hospitals trust" campaign as misleading. AHP does not charge that it contains any false statements but that it gives the false impression that hospitals dispense more Tylenol than other pain relievers because it is safer or more effective, whereas they actually do so only because McNeil supplies Tylenol to hospitals at very low prices.

There is indeed a clear implication in the "hospitals trust" commercials that hospitals approve Tylenol's efficacy and safety. Otherwise, they surely wouldn't dispense so much of it. The consumer surveys which AHP conducted to establish this point were altogether unnecessary, although it is interesting to note that when AHP wanted to prove the obvious, it risked open-ended questions rather than the grossly suggestive multiple choice questions it employed when it was less confident of the results.

There is nothing false in the disputed implication. Hospitals surely wouldn't dispense an analgesic that is ineffective or unsafe, no matter how cheaply they can buy it. At worst, the statement is a half-truth, in that it omits to mention that hospitals choose Tylenol for the additional reason that it costs less than competitive analgesics. The Court finds that this omission does not

make the "hospitals trust" commercials unfair. There is nothing to prevent AHP from matching McNeil's prices to hospitals. Indeed AHP itself employs the identical marketing stratagem when it inundates physicians with free samples of Anacin–3, follows up with inquiries as to whether any of the samples were given to patients and then trumpets that X-thousand doctors have recommended Anacin–3.

AHP complains that the "hospitals trust" commercials are misleading for the additional reason that they give the impression that Tylenol is different from all the other OTC pain relievers, whereas AHP's Anacin–3 is also acetaminophen and identical to Tylenol in every significant respect. But this is standard operating procedure in the consumer drug market. Sterling Drug, for example, does not tell the public that Bayer is only one of many aspirins that are chemically identical and of comparable purity, nor does anyone seriously contend that it should be required to do so. Instead it merely advertises that more doctors use Bayer than any other pain reliever.

The failure of consumers to appreciate that Anacin–3 is an acetaminophen product is the fault of no one but AHP. AHP's decision to give it a name so similar to that of its aspirin-caffeine product, Anacin, may be more to blame than the responsible AHP executives would care to admit.

Struggling against this self-inflicted problem of brand confusion, AHP has attempted to hitchhike on Tylenol's hospital acceptance by advertising that Anacin–3 contains "the aspirin-free pain reliever hospitals use most." How typical it is of the infighting in the industry that at the very time AHP complains that McNeil is taking unfair advantage of its discount-induced hospital popularity, AHP is itself trying to get a free ride on it.

Counterclaims

As might be expected, McNeil has counterattacked, asserting that a number of ***587** AHP's advertising claims are false or misleading.

Anacin's "no stomach upset" claims

[11] Although on its packages of Advil and Anacin–3, AHP prominently display their active ingredients, ibuprofen and acetaminophen respectively, on its Anacin package, the word aspirin is buried in the small print on the back. And for many years, until the FDA required it to do so, AHP never mentioned the word aspirin in its Anacin advertising. Obviously, and quite understandably, AHP has sought to distance the product from aspirin's unsavory reputation for adverse side effects.

But McNeil claims that AHP has crossed the line dividing mere non-disclosure from outright falsehood by broadcasting a series of television commercials in which an actor, portraying an ordinary Anacin user, says, in substance, "My headache's gone, and Anacin didn't upset my stomach."

McNeil argues that these commercials convey the false impression that Anacin causes less stomach upset than other OTC pain relievers including acetaminophen and ibuprofen. McNeil reads too much into the campaign message. All it literally communicates is that one user got pain relief without stomach upset. Even though there is an implication that the one user represented is typical, that implication is true. Although the aspirin-based products are clearly the worst of the OTC analgesics from the standpoint of gastric irritation, only a small percentage of Anacin users suffer any consequent gastric discomfort.

McNeil argues that there is the further implication that Anacin cause less stomach distress than non-aspirin pain relievers. The Court finds that no such message is conveyed. McNeil attempted to support this interpretation of the Anacin commercials by two surveys of consumers. But those surveys, like most of the others in evidence, were not convincing, because the pivotal multiple choice questions did not include, among the options presented, a literally accurate description of the message conveyed. Respondents were not given, as a positive choice, a statement to the effect that the commercial communicates the message that Anacin is unlikely to cause stomach upset, without comparing it in this respect with non-aspirin pain relievers. Instead they were asked to choose from a series of improbable descriptions, including one in each survey which, although factually true, was so alien to the message literally conveyed as to be downright fatuous: "Anacin is more likely to cause stomach upset than aspirin-free pain relievers." Anyone who really believes that AHP is spending a fortune to disseminate *that* message has not been listening to pain-reliever commercials—which means

that he must be freshly arrived from another galaxy. Yet 4.9% of the respondents in one survey and 8% in the other selected that option. So much for the reliability of closed-end survey questions.

The Court finds that Anacin's "no stomach upset" advertising is within the acceptable and expectable limits of commercial puffery and is therefore unlikely to mislead consumers.

Doctors' recommendation claims

AHP ran a series of advertisements claiming that doctors have recommended Advil "over one million times for headaches and other kinds of pain." In later advertisements, the number has been raised, in McDonald's fashion, to "five million."

McNeil protests that the phrase "headaches and other kinds of pain" is misleading because, the singling out of headache for special mention creates the impression that most of the recommendations were for headache, whereas through the first quarter of 1986, only 2.4% of doctors' recommendations of Advil were for headache.

The Court finds that AHP's "doctors' recommendation" claims are neither false nor intolerably misleading.

The "70,000 doctors" campaign

[12] To counter McNeil's "hospitals trust" campaign, AHP conceived and executed a campaign to establish Anacin–3 as the pain reliever recommended by physicians. AHP began by mailing free samples of Anacin–3 to 250,000 doctors and dentists, ***588** together with a business return post card which could be mailed in to request additional free samples. 108,000 of the recipients returned the post cards. AHP conducted a survey of 404 of this group, a sample of only four-tenths of one percent. 263, or 65% of the sample, said that they had recommended Anacin–3. Multiplying 108,000 by 65%, AHP computed that over 70,000 doctors and dentists had recommended Anacin–3.

McNeil has attacked this campaign as misleading in that it creates the false impression that most doctors recommend Anacin–3, whereas 70,000 doctors represents only about 10% of the total in this country. McNeil relies on surveys to prove that a majority of the public reading or hearing the claim got the impression that "most" doctors recommend Anacin–3. The Court is not persuaded by that argument. Assuming that extrapolation from a sample of 0.4% is reliable, as the experts claim and as the Court accepts, it is true that 70,000 doctors recommended Anacin–3. AHP should be allowed to say so, regardless of whether most laymen have no idea as to the percentage of doctors that number represents.

[13] A more troublesome problem with the "70,000 doctors" campaign is that the 70,000 doctors did not spontaneously recommend Anacin–3. Very likely, all that most of them did was to pass on to patients free samples which AHP had furnished them. This, of course, implies a recommendation of the product. But it is certainly not a recommendation based on a preference for Anacin–3 over Tylenol or other acetaminophen pain relievers, or even necessarily over Advil or Medipren. Anacin–3 was selected because it was at hand and because it was free.

But the unassailable fact remains that 70,000 doctors and dentists did at least impliedly recommend Anacin–3. That a lesser number might have spontaneously recommended Anacin–3 is not any more a fatal falsity than is the fact that in McNeil's "hospitals trust" campaign the hospitals undoubtedly would dispense less Tylenol if it did not cost them substantially less than other non-aspirin pain relievers. What AHP has done is to carry McNeil's scheme to its logical extreme and cut the price of Anacin–3 to doctors all the way to zero.

The Court accordingly finds that the "70,000 doctors" campaign is not false or unacceptably misleading.

The "three good reasons" advertisements

[14] AHP has run a series of print advertisements stating that hospitals recommend "acetaminophen, the aspirin-free pain reliever in Anacin–3, more than any other pain reliever," and that doctors and pharmacists also recommend it. McNeil complains that since most consumers don't know that Tylenol is acetaminophen, they are misled into believing that the hospitals, doctors and pharmacists are recommending Anacin–3 in preference to Tylenol.

The Court agrees. What the hospitals have really recommended is not the generic drug acetaminophen, but the specific proprietary product, Tylenol (although their recommendation, as previously noted, is surely influenced by the low price at which Tylenol is available to them). The

statement that hospitals recommend acetaminophen more than any other pain reliever has a tendency to mislead readers.

This tendency of the advertisements to mislead is exacerbated by the fact that they refer by name to Anacin–3 without mentioning that other OTC acetaminophen products are available, much less that one of these competitive products is actually what the hospitals have recommended. The result is that many readers are surely led to believe that Anacin–3 has been specifically recommended, and that this implies a preference for that product over Tylenol.

This was confirmed by a survey conducted by McNeil, in which respondents were asked the open-ended question "What pain reliever does the ad communicate to you that doctors are recommending? 43.9% of the respondents answered 'Anacin–3.' " When they were asked what they understood ***589** by the reference to "any other aspirin-free pain reliever," 39.3% answered "Tylenol."

Surprisingly, AHP has criticized this survey by contending that the questions should have been in closed-end or multiple-choice form. If they had been, AHP would doubtless be attacking them, and with much sounder reason, as being unfairly suggestive.

The Court accordingly finds that the "three reasons" advertisements are misleading and unfair. They could properly have been reworded to state, in effect: "Hospitals have recommended a product containing acetaminophen more than all other types of pain reliever combined. Anacin–3 contains acetaminophen."

Pediatric overdose claims

AHP has issued press releases warning of the danger of poisoning of small children by household chemicals or an accidental overdose of medicines, stating in part:

> The typical poisoning scenario goes something like this: a child under five years old is playing, unsupervised by busy parents, between 4:00 and 8:00 P.M.—the time of day that has come to be known as the 'arsenic hours'. The child gets hold of a bottle of medicine or a cleaning product and it is discovered when he or she begins to vomit or cough and choke. In many instances, the product has been left out within easy reach because the adult is using it or expects to use it soon.

McNeil asserts that these press releases accuse acetaminophen as the analgesic principally responsible for injury or death of children from accidental drug overdose and promotes Advil as a means of reducing this hazard. McNeil challenges this alleged advantage, contending that an overdose of acetaminophen is no more dangerous to children than an overdose of ibuprofen because children are more resistant to hepatoxicity than adults.

McNeil again reads too much into AHP's press releases. All they actually say is that acetaminophen poses a more serious threat from overdose than ibuprofen does which, as previously noted, is true as a general proposition. Then, in a separate portion of the press releases, there is the above-quoted passage which discusses the obvious danger of accidental ingestion by children of all kinds of drugs and household chemicals. Analgesics are not specifically mentioned in this passage, much less is there any suggestion that one analgesic is more dangerous to children than another.

The Court finds no impropriety in the press releases.

Drug-drug interaction claims

AHP has published in medical journals advertisements claiming that Advil interacts with fewer drugs than acetaminophen. In one of these advertisements, there is a footnote citation of "Data on file, Medical Department, Whitehall Laboratories."

The alleged "data on file" were not produced at the trial or in pretrial discovery. Instead, Whitehall's Medical Director, Dr. Edward Henry, testified that the data were contained in Whitehall's medical library, to which anyone asking to see the data would be admitted. Dr. Henry specifically identified a textbook by Dr. Hansten as supporting the claim. When asked why it was not specifically identified in the footnote, he ventured the preposterous suggestion that the copyright laws might prohibit such a citation (although such citations are a

common feature of advertisements directed to medical professionals as Dr. Henry surely knows).

The truth of the matter is that there simply is no credible support for AHP's claim of Advil's superiority over Tylenol in the respect of drug-drug interactions, as AHP's own expert, Dr. Lasagna, admitted at the trial. Indeed, as discussed above, the truth is just the opposite.

AHP's drug-drug interaction claims are clearly false.

The Applicable Law

The basic legal principles applicable in this case are not in dispute.

***590** Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), prohibits:

> any false description or representation, including words or other symbols tending falsely to describe or represent ... goods....

This statute has been given a broad application to further "the clear purpose of Congress in protecting the consumer." *Vidal Sassoon, Inc. v. Bristol-Myers Co.,* 661 F.2d 272, 277 (2d Cir.1981).

[15] A violation of section 43(a) is established by proving either that an advertisement is literally false, or that it has a tendency to mislead or deceive. *American Home Products Corp. v. Johnson & Johnson,* 577 F.2d 160, 165–166 (2d Cir.1978).

[16] **[17]** In determining whether an advertisement is misleading, the Court must first consider its literal meaning, then determine whether it conveys to the particular audience at which it was directed any implied message beyond its literal meaning. *Avis Rent A Car System, Inc. v. Hertz Corp.,* 782 F.2d 381 (2d Cir.1986); *American Home Products v. Johnson & Johnson, supra,* 577 F.2d at 165. Once the meaning of the advertisement to the target audience has been determined, the Court, as the finder of fact, must then judge for itself whether the evidence establishes that readers are likely to be misled. *McNeilab, Inc. v. American Home Products Corp.,* 501 F.Supp. 517, 525 (S.D.N.Y.1980). It is not required to establish that a majority of the target audience is apt to be misled—only that a "not insubstantial number" are likely to be. *Id.* at 528.

[18] This determination is based upon the overall impression created by the advertisement. If the advertisement contains a definition or disclaimer which purports to change the apparent meaning of the claims and render them literally truthful, but which is so inconspicuously located or in such fine print that readers tend to overlook it, it will not remedy the misleading nature of the claims. *Giant Foods, Inc. v. FTC,* 322 F.2d 977, 986 (D.C.Cir.1963), *cert. dismissed,* 376 U.S. 967, 84 S.Ct. 1121, 12 L.Ed.2d 1121 (1964).

[19] **[20]** The meaning of an advertisement to its target audience may be established by properly designed and conducted surveys. The probative value of a survey depends entirely upon its fundamental fairness and objectivity, which in turn depends upon many factors, such as whether it is properly "filtered" to screen out those who got no message from the advertisement, whether the questions are directed to the real issues, and whether the questions are leading or suggestive. *Amstar Corp., Inc. v. Domino's Pizza, Inc.,* 615 F.2d 252, 254 (5th Cir.), *cert. denied,* 449 U.S. 899, 101 S.Ct. 268, 66 L.Ed.2d 129 (1980); *Upjohn Co. v. American Home Products Corp.,* 598 F.Supp. 550, 559–60 (S.D.N.Y.1984).

[21] In an action under section 43(a), the

> plaintiff bears the burden of showing that the challenged advertisement is false and misleading, not merely that it is unsubstantiated by acceptable tests or other proof.

Procter & Gamble Co. v. Chesebrough-Ponds, Inc., 747 F.2d 114, 119 (2d Cir.1984) (citation omitted). However, an advertisement violates section 43(a) if, in ostensible support of claims made therein, it cites authorities which do not in fact support the claim.

[22] **[23]** There is a strong public interest in the prevention of misleading advertisements, *Coca-Cola Co. v. Tropicana Products, Inc.,* 690 F.2d 312, 317 (2d Cir.1982), and this interest is particularly strong where OTC drugs are concerned. *Upjohn Co. v. American Home Products Corp., supra,* 598 F.Supp. at 557; *McNeilab, Inc. v. American Home Products Corp., supra,* 501

F.Supp. at 539–40. Where the advertising in question is misleading, this interest prevails over the advertiser's right of commercial speech.

[24] **[25]** Because of this keen public interest, a defense of unclean hands can be established only by "clear, unequivocal and convincing" evidence. *Nike, Inc. v. Rubber* ***591** *Mfrs. Ass'n, Inc.,* 509 F.Supp. 919, 926 (S.D.N.Y.1981). Likewise, the defense of laches should be sparingly applied. *See Grotrian, Helfferich, Schulz, Th. Steinweg Nachf. v. Steinway & Sons,* 523 F.2d 1331, 1343–44 (2d Cir.1975).

Conclusions

The Court concludes that McNeil has violated section 43(a) of the Lanham Act by advertisements:

(1) falsely indicating (by the use of check marks for ibuprofen and asterisks for aspirin) that ibuprofen tends more than aspirin to cause the CNS side effects of dizziness, nervousness, headache and drowsiness;

(2) misleadingly suggesting that ibuprofen and aspirin are comparable in their tendency to cause adverse gastrointestinal side effects by using check marks for both in a checklist in which the definition of a check mark as indicating occurrence only and not incidence is in much smaller type in a footnote and in which aspirin and ibuprofen are grouped together on one side of a heavier line separating them from acetaminophen;

(3) misleadingly exaggerating the superiority of acetaminophen over ibuprofen with respect to their relative tendencies to cause renal dysfunction by using a check mark for ibuprofen and not even an asterisk (indicating a "relatively rare" effect) for acetaminophen;

(4) purportedly presenting "safety profiles" for OTC analgesics which exclude all side effects, such as hepatotoxicity and overdose hazard, as to which ibuprofen is superior;

(5) misleadingly suggesting that ibuprofen and aspirin are comparable in their adverse side effects by linking them together and adversely comparing them indiscriminately to acetaminophen, particularly when accompanied by dramatic and distasteful analogies, such as rotten fruit;

(6) misleadingly suggesting that ibuprofen is as likely to cause stomach upset as aspirin, for example by referring to "the" stomach upset caused by aspirin or ibuprofen; and

(7) falsely claiming, with reference to Extra-Strength Tylenol, that "you can't buy a more potent pain reliever without a prescription" (although it would not be false or misleading to claim that for mild-to-moderate pain, you can't buy a more effective pain reliever).

The Court further concludes that AHP has violated section 43(a) by advertisements:

(1) misleadingly stating that "hospitals recommend acetaminophen, the aspirin-free pain reliever in Anacin–3, more than any other pain reliever" (although it would not be misleading to state that "[H]ospitals have recommended a product containing acetaminophen more than any other type of pain reliever. Anacin–3 contains acetaminophen.");

(2) falsely claiming that Advil is less susceptible than acetaminophen to adverse drug-drug interactions;

(3) citing, in ostensible support of claims of efficacy or safety, "data on file," where the alleged support can readily be identified more precisely, particularly when it consists of widely available texts or technical journals.

An injunction will issue to prevent a continuation or resumption of the foregoing advertising practices. The parties are directed to cooperate in drafting a proposed judgment or, if agreement cannot be reached, to submit separate proposals to the Court.

The Court concludes that, in all of the other respects discussed above, no violation of the Lanham Act has been established. The parties have not pressed their claims under the New York General Business Law or the common law, and have rested their cases on the Lanham Act alone.

The Court further concludes that, because of the public interest involved, injunctive relief should not be denied because of unclean hands or laches. However, the Court is inclined to believe that, because both parties have been guilty of false and ***592** misleading advertising, and because it appears virtually impossible to prove, with

any degree of reliability, the resulting damages each has sustained through lost sales, profits and good will, the amount of net damages which is likely to be awarded is insufficient to justify the substantial expense of a trial on the issue of damages. If either party feels otherwise, it may contact the Court and a conference will be scheduled to plan the further conduct of the action.

SO ORDERED.

All Citations

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