99-9501

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 99-9501

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P.,

Plaintiff-Appellant,

– v. –

WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., and CIRCA PHARMACEUTICALS, INC.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR THE UNITED STATES AS *AMICUS CURIAE*

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PRELIMINARY STATEMENT

Pursuant to 28 U.S.C. § 517 and Rule 29(a) of the Federal Rules of Appellate Procedure, as well as this Court's order of January 10, 2000, the United States submits this brief as amicus curiae.

In the Hatch-Waxman Amendments of 1984, Congress provided a streamlined mechanism for approval of generic drugs, requiring that the federal Food and Drug Administration (FDA) determine that a generic drug is, for therapeutic purposes, the same as a brand-name, or pioneer, drug. That determination specifically means that the generic drug is equally safe and effective as the pioneer drug under the same conditions of use (which are set out in the FDA-approved labeling). As part of that statutory scheme, Congress also required that the labeling for the generic drug must

be "the same as the labeling approved" by FDA for the pioneer. 21 U.S.C. § 355(j)(2)(A)(v). SmithKline's argument in this copyright-infringement case would undermine that requirement.

SmithKline's legal theory in this case threatens the regulatory authority of FDA and the achievement of the important public health goals of the Hatch-Waxman scheme. SmithKline's argument fails to recognize that copyright law -- through the doctrine of implied, nonexclusive license -- provides a means of reconciling copyright law with the mandate of the Hatch-Waxman Amendments. As discussed below, this brief is being filed to eliminate any confusion regarding the Government's position, and to inform the Court that FDA is taking any necessary steps to be certain that its actions are consistent with that position.

INTEREST OF THE UNITED STATES

The Federal Government, through FDA, is responsible for regulating drugs, including the review and approval of both pioneer and generic drugs, as set forth in the Federal Food, Drug & Cosmetic Act (FD&C Act). See, e.g., 21 U.S.C. §§ 371-377; 21 C.F.R. § 5.10. The FD&C Act's comprehensive scheme of drug regulation is designed to ensure that drugs on the market are safe and effective for the conditions of their use, as set forth in the FDA-approved labeling. The FD&C Act, as amended in 1984 by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (popularly known as the Hatch-Waxman Amendments), provides a streamlined mechanism for approval of generic drugs.

The Federal Government also has a compelling interest in the proper interpretation of copyright law. The Constitution commits copyright protection to the hands of Congress, and federal law has guaranteed the protection of original works of expression, most recently in the Copyright Act of 1976. The United States is a world leader in international efforts to preserve and protect intellectual property rights, including copyright, against improper encroachment.

STATEMENT OF THE CASE

A. Nature of the Case

In this copyright infringement claim, SmithKline seeks to prevent a generic competitor from using the FDA-approved labeling for SmithKline's pioneer drug, Nicorette. In 1996, FDA approved Nicorette for over-the-counter sales, reviewing and approving a user's guide and audiotape as labeling materials that would provide consumers with information bearing on the safe and effective use of the drug. After Nicorette's patent protection and additional period of market exclusivity expired, Watson sought to introduce generic competition for Nicorette, and FDA required that Watson include labeling materials -- a user's guide and audiotape -- that in many respects duplicated the materials previously approved for Nicorette.

SmithKline brought this copyright infringement claim against Watson, claiming that the labeling materials approved by FDA for Watson's generic version of Nicorette infringed SmithKline's copyright on the FDA-approved labeling materials for Nicorette. The United States is not a party to this suit, nor has SmithKline sued the Government to litigate any related claims.

The district court initially entered a preliminary injunction against Watson's use of assertedly infringing labeling materials. After hearing from FDA in an informal capacity, however, and after Watson sought FDA approval of modified labeling materials, the district court lifted the preliminary injunction. That decision was based in large part on the district court's revised understanding that FDA would not allow Watson to vary its labeling substantially from the labeling approved for Nicorette. The decision lifting the preliminary injunction is the subject of this appeal.

B. Statutory and Regulatory Scheme

1. Copyright

Pursuant to explicit constitutional authority, the Copyright Act of 1976 establishes a comprehensive federal scheme governing the intellectual property protection of literary, musical, and other works. See 17 U.S.C. §§ 101 et seq.; see also U.S. Const., art. I, § 8, cl. 8. The purpose of this important federal scheme is to secure certain exclusive rights for copyright owners -- specifically, the exclusive rights to reproduce, distribute, perform, and display copyrighted material, and the exclusive right to prepare derivative works. See 17 U.S.C. § 106. The Copyright Act also guarantees the right to be free from infringement, which is defined as a violation of any of the enumerated exclusive rights. Id. § 501(a).

Copyright protection extends to "original works of authorship fixed in any tangible medium of expression * * * from which they can be perceived, reproduced, or otherwise communicated." 17 U.S.C. § 102(a). But "facts are not copyrightable," a principle that is "universally understood." Feist Publications, Inc. v. Rural Tel.

Serv. Co., 499 U.S. 340, 344 (1991); see also 17 U.S.C. § 102(b) (copyright protection does not "extend to any idea, procedure, * * * concept, principle, or discovery"). "No author may copyright his ideas or the facts he narrates." Harper & Row, Publishers, Inc. v. Nation Enterprises, 471 U.S. 539, 556 (1985).

Copyright protection for works made for hire after January 1, 1978, "endures for a term of 95 years from the year of its first publication, or a term of 120 years from the year of its creation, whichever expires first." 17 U.S.C. § 302(c).

2. FD&C Act

The FD&C Act prohibits the sale of any new drug unless it has first been approved by FDA. 21 U.S.C. § 355(a); Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 612-613 (1973). A new drug normally obtains FDA approval by virtue of a "new drug application" (NDA), which must demonstrate that the drug is safe and effective for its intended uses. 21 U.S.C. § 355(b). An NDA must include, among other things, samples of the drug and its proposed labeling materials, as well as extensive studies, including both laboratory and clinical investigations, to show that the drug is safe and effective for the uses listed on the label. Id.; see also 21 C.F.R. § 314.50 (detailing contents of NDA).

The Hatch-Waxman Amendments provide an important exception to the NDA requirement. Under that exception, generic drugs can be approved without the submission of extensive, detailed scientific studies demonstrating safety and efficacy. A generic drug is one that is, for all relevant purposes, the same as a brand-name, or "pioneer," drug. See generally United States v. Generix Drug Corp., 460 U.S. 453,

454-455, 461 (1983). A generic version of an approved pioneer drug may obtain FDA approval by filing an "abbreviated new drug application" (ANDA), which allows the generic to "rely on the safety and effectiveness studies submitted by the pioneer applicant." Purepac Pharm. Co. v. Friedman, 162 F.3d 1201, 1202 (D.C. Cir. 1998).

A generic drug applicant demonstrates that it is entitled to rely on the pioneer's studies by proving that the generic drug is "the same or therapeutically equivalent to the drug which has already been approved." H.R. Rep. No. 98-857 (part II) (1984), at 5, reprinted in 1984 U.S.C.C.A.N. 2686, 2689. In particular, an ANDA must show that the labeling proposed for the generic drug is "the same as the labeling approved for" the pioneer drug. 21 U.S.C. § 355(j)(2)(A)(v). The same-labeling requirement includes an exception that allows "changes required * * * because the new drug and the listed drug are produced or distributed by different manufacturers." Id.[1]

The FD&C Act defines labeling broadly to include "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C.§ 321(m).[2] FDA's regulatory interpretation of that provision provides examples of the breadth of the statutory definition, including "[b]rochures, booklets, * * * sound recordings, * * * and similar pieces of

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[1] The statute also includes another exception, for changes authorized by petition to FDA. See 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.93. That provision is not at issue here.

[2] The statute defines "label" to "mean[] a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k).

printed, audio, or visual matter descriptive of a drug." 21 C.F.R. § 202.1(l)(2). In addition, the definition encompasses such references as the Physicians' Desk Reference. Id.

The Hatch-Waxman Amendments embody Congress's purpose of "increas[ing] competition in the drug industry by facilitating the approval of generic copies of drugs." Mead Johnson Pharm. Group v. Bowen, 838 F.2d 1332, 1333 (D.C. Cir. 1988). Congress likewise gave a substantial benefit to pioneer drug manufacturers, guaranteeing an additional period of market exclusivity, in addition to patent protection. See 35 U.S.C. § 156; Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669-671 (1990). "Congress struck a balance between expediting generic drug applications and protecting the interests of the original drug manufacturers." Abbott Labs. v. Young, 920 F.2d 984, 985 (D.C. Cir. 1990), cert. denied, 502 U.S. 819 (1991); see also, e.g., Bristol-Myers Squibb Co. v. Shalala, 91 F.3d 1493 (D.C. Cir. 1996).

SUMMARY OF ARGUMENT

The Hatch-Waxman Amendments require that a generic drug have the same labeling as the labeling approved for the pioneer drug on which the generic is based. FDA has concluded that the statute's same-labeling provision requires that the generic drug's labeling be identical. The minor differences FDA allows under its interpretation of the different-manufacturer exception are carefully cabined to avoid suggesting any therapeutic difference between the pioneer and generic drugs.

SmithKline appears to concede that, in most instances, the Hatch-Waxman Amendments require generic labeling materials to be identical to the labeling approved by FDA for the pioneer drug. SmithKline Br. 6, 45. But SmithKline asserts that the rule should be different here because its approved labeling materials -- the user's guide and audiotape -- contain creative expressions entitled to copyright protection. Id. That argument appears to be based on an assumption that the same-labeling requirement should yield where the FDA-approved labeling includes copyrighted materials. That fundamental premise is incorrect.

The clear mandate of the Hatch-Waxman Amendments is not in conflict with the Copyright Act. When a pioneer drug manufacturer submits proposed labeling to FDA for the agency's approval of that labeling in conjunction with an NDA, the Hatch-Waxman Amendments clearly contemplate that the FDA-approved labeling will be required for a later generic competitor. If a pioneer drug manufacturer chooses to submit copyrighted material as part of its proposed labeling, that manufacturer cannot later assert that copyright law forms a basis for preventing the operation of the same-labeling requirement in the Hatch-Waxman Amendments.

Copyright law provides that a copyright holder can be understood to grant an implied, nonexclusive license. Here, the Hatch-Waxman Amendments provide that FDA-approved labeling will be used by a generic competitor. SmithKline's submission of copyrighted material to FDA, as part of the effort to obtain approval for over-the-counter sales of Nicorette, consequently must be understood as the grant of a license for later use of that material by Watson for its generic version of

Nicorette. Such an implied license is narrow -- extending only to approved ANDA holders, and authorizing only the limited use contemplated by the Hatch-Waxman Amendments. Moreover, this interpretation is based on the specific requirement of of the Hatch-Waxman Amendments, as interpreted by FDA, and the interaction of that congressional mandate with copyright law. The narrow implied-license approach urged in this brief does not undermine copyright protections.

Here, SmithKline voluntarily submitted its user's guide and audiotape to FDA as proposed labeling. SmithKline was not compelled to use creative versions of those materials (although FDA could have required the development of particular materials as a condition of approval). And SmithKline knew then that the user's guide and audiotape were considered by FDA to be the approved labeling for Nicorette. In those circumstances, it would be wholly inappropriate to allow SmithKline to invoke copyright law to block the same-labeling requirement of the Hatch-Waxman Amendments.

FDA-approved labeling is not set in stone, however. A pioneer drug manufacturer could seek FDA approval for amended labeling. FDA would review such an application to determine whether the amended labeling would suffice for the safe and effective use of the drug for its intended uses. If FDA were to approve amended labeling for Nicorette, Watson would be required to adopt the changes as well. In this way, SmithKline could protect its copyright for certain materials, if those materials indeed are not necessary for FDA approval. Unless FDA approves a change for SmithKline's approved labeling, however, the user's guide and audiotape

remain subject to the same-labeling law in their entirety, with only the exceptions allowed by FDA regulation.

ARGUMENT

POINT I

CONGRESS REQUIRED GENERIC DRUG LABELING TO BE "THE SAME" AS THE LABELING APPROVED BY FDA FOR THE PIONEER DRUG

The Hatch-Waxman Amendments require that the labeling of a generic drug must be "the same as the labeling approved for the [pioneer] drug." 21 U.S.C. § 355(j)(2)(A)(v). There is no mention of copyright in the statute, and nothing expressly or by direct implication creates an exception for copyrighted materials that are included in the FDA-approved labeling. FDA has interpreted the statutory language to mean precisely what it says, that there can be no variation in language, structure, or format, other than the narrow changes contemplated by the different-manufacturer exception.

SmithKline suggests that the statutory phrase -- "the same" -- "does not require that the labeling be 'identical.'" SmithKline Br. 39. SmithKline would interpret the language of the Hatch-Waxman Amendments to require only "that the [generic] drug's labeling convey to consumers all facts and information relating to the safe and effective use of the product at issue, not that it copy verbatim the precise manner in which this information is expressed by the listed drug's copyrighted labeling." Id. at 42. FDA has rejected that reading of the statute, and the agency's understanding is controlling, particularly in this litigation.

As a matter of plain language, the statutory term "same" is most readily understood to require identical words. See, e.g., Random House Dictionary 1697 (2d ed. unabr. 1987) ("identical with"; "being one or identical though having different names, aspects, etc."); Webster's Third New Int'l Dictionary 2007 (unabr. 1967) ("resembling in every way"; "without addition, change, or discontinuance"; "IDENTICAL, SELFSAME"). Although the word "same" might also be used where a variation in expression is permissible, there is no indication Congress intended that sense in this statute.

That natural reading of the statutory language is confirmed by the purposes of the statute. Generic drugs are desirable because, for therapeutic purposes, they are interchangeable with (that is, substitutable for) the pioneer drug on which they are based. In terms of safety and efficacy, there is no difference between the two, and this point is at the heart of the generic drug regulatory scheme. The pioneer drug's NDA includes the only clinical studies for either drug, and FDA's findings of safety and efficacy, based on those studies, justify approval of the generic drug as well. Allowing differences in labeling could undermine that equivalence, potentially misleading consumers to believe that the pioneer and generic drug products were therapeutically different; that misconception could raise questions in the public's mind regarding the relative therapeutic value of innovator and generic drugs. Such a result would be inconsistent with a fundamental purpose of the Hatch-Waxman Amendments -- the goal of encouraging competition by the introduction of drugs that

"are the same as the listed drug." H.R. Rep. No. 98-857 (part I), at 21 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2654.

The statutory same-labeling requirement is subject to an exception for "changes required * * * because the new drug and the [pioneer] drug are produced or distributed by different manufacturers." 21 U.S.C. § 355(j)(2)(A)(v). FDA, in implementing the statute, has canvassed the evidence of legislative intent, considered comments from interested parties, compared alternative constructions, and concluded that the different-manufacturer exception permits only a narrow category of changes, as described in the FDA regulation implementing that statutory exception. See 21 C.F.R. § 314.94(a)(8)(iv). That view is entitled to deference. See Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-843 (1984); Serono Lab., Inc. v. Shalala, 158 F.3d 1313, 1320-1321 (D.C. Cir. 1998).

FDA has concluded that the different-manufacturer exception encompasses only a limited number of changes, including "differences in expiration date, formulation, bioavailability, or pharmacokinetics." 21 C.F.R. § 314.94(a)(8)(iv). Each of those differences is necessary to reflect physical differences, such as different inactive ingredients. Accuracy requires that the label reflect the correct ingredients and formulation. The applicable House Report noted that "[t]he FDA might require the listed drug maker to specify the color in its label. The generic manufacturer, which has used a different color, would have to specify a different color in its label." H.R. Rep. No. 98-857 (part I), at 22, reprinted in 1984 U.S.C.C.A.N. 2647, 2655. FDA also allows "labeling revisions made to comply with current FDA labeling

guidelines or other guidance," thereby ensuring that the most current regulatory requirements are reflected in the generic drug's label, even if the pioneer's label has not yet been updated. 21 C.F.R. § 314.94(a)(8)(iv).

Finally, FDA allows "omission of an indication or other aspect of labeling protected by patent or accorded exclusivity" by the Hatch-Waxman Amendments. Id. While a pioneer drug might still have market exclusivity for one or more newer indications, even after the patent protection and market exclusivity as to the original indications had expired, a generic drug could be entitled to ANDA approval for the original indications. The D.C. Circuit noted that the language and structure of the Hatch-Waxman Amendments supported FDA's interpretation. See Bristol-Myers, 91 F.3d at 1500.

"[T]he exceptions to the requirement that a generic drug's labeling be the same as that of the [pioneer] drug are limited." 54 Fed. Reg. 28872, 28884 (1989). FDA rejected the idea that differences could include more "significant changes in labeling." Id. FDA later rejected comments that urged greater latitude in labeling differences intended to provide additional safety-related information. See 57 Fed. Reg. 17950, 17961 (1992). FDA emphasized that the generic drug's "labeling must be the same as the [pioneer] drug product's labeling because the [pioneer] drug product is the basis for ANDA approval." Id.

The ANDA procedure, established by the Hatch-Waxman Amendments, provides for streamlined approval of generic drugs and represents a recognition that a generic drug manufacturer need not present the full panoply of clinical trials and

other rigorous, scientific studies that are normally required to demonstrate safety and efficacy. Instead, a generic drug need only show that it is not meaningfully different from its pioneer counterpart. Once the two drugs are shown to be the same for therapeutic purposes, FDA can rely on its earlier determination that the pioneer drug is safe and effective.

Labeling materials -- such as instructions for use and warnings -- define the conditions for use of the drug product. See 21 U.S.C. § 355(d)(1) (NDA must demonstrate, by clinical and other tests, that the drug "is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling" of the drug); id. § 355(d)(5) (similar requirement for a showing that the drug is effective under the conditions set out in the proposed labeling). FDA has reasonably determined that the kinds of changes SmithKline proposes could easily undermine FDA's determination that the two products are equally safe and effective for the same conditions of use. "Consistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart." 57 Fed. Reg. 17950, 17961. Any differences in labeling will threaten the therapeutic identity of the two products:

> FDA believes that a generic drug product approved on the basis of studies conducted on the [pioneer] drug and whose labeling is inconsistent with the [pioneer] drug's labeling might not be considered safe and effective for use under the conditions prescribed, suggested, or recommended in the [pioneer] drug's labeling.

Id. Approval of an ANDA means that FDA has concluded that the generic drug is equally safe and effective for the same conditions of use as the pioneer drug. That

conclusion could easily be undermined in the minds of consumers and health professionals if the labeling differs, even slightly, in such significant matters as directions for use.[3] Here, too, FDA is entitled to substantial deference in its construction of the statute it administers.

In sum, the Hatch-Waxman Amendments establish a mechanism to ensure efficient approval of generic competition, without sacrificing public health and safety concerns. An integral part of that scheme requires that the generic drug include the same labeling -- which describes the conditions of use under which the drug is safe and effective -- that was approved for the pioneer.

POINT II

COPYRIGHT LAW IS CONSISTENT WITH THE HATCH-WAXMAN AMENDMENTS

SmithKline assumes that the same-labeling requirement -- as construed by FDA, to allow only those minor deviations required by manufacturing differences -- conflicts with the Copyright Act. According to SmithKline's view, the Hatch-Waxman Amendments should be construed differently to avoid such a conflict. But there is no basis for either conclusion.

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[3] SmithKline (Reply Br. 20, 25-26) urges that Watson could use another form of the NDA procedure (21 U.S.C. § 355(b)(2)) to seek approval based on SmithKline's clinical and laboratory data, combined with other studies proving that different labeling materials are sufficient to show safety and efficacy. It is not necessary to consider whether that option is open to Watson. As SmithKline implicitly acknowledges, a § 355(b)(2) NDA is not an ANDA. The ANDA procedure established by the Hatch-Waxman Amendments does not require -- indeed, does not allow -- approval based on different clinical studies. Congress enacted the ANDA procedure so that generic drugs would not be required to rely on such studies.

FDA has properly interpreted the clear mandate of Congress, concluding that labeling submitted to FDA and approved as part of a pioneer drug's NDA will be used, with only very minor changes, for a generic drug when FDA later approves an ANDA. But the Court need not reach the question whether that requirement of the Hatch-Waxman Amendments conflicts with copyright law, because the copyright doctrine of implied, nonexclusive license readily accommodates the same-labeling requirement. A pioneer manufacturer (such as SmithKline) does not lose its copyright protections in FDA-approved labeling, but it must be understood to have impliedly consented to the use of that labeling by a generic competitor, as mandated by the Hatch-Waxman Amendments.

Such an interpretation is not a repeal by implication: "Th[e] classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." United States v. Fausto, 484 U.S. 439, 453 (1988); see also NLRB v. Drivers, Chauffeurs, Helpers, Local Union, 362 U.S. 274, 291-292 (1960) ("[c]ourts may properly take into account the later Act when asked to extend the reach of the earlier Act's vague language"). The Hatch-Waxman Amendments do not override the Copyright Act, but they do provide a statutory background against which submission of materials for FDA approval must be understood.

Submission of copyrighted materials for federal agency approval does not deprive those materials of copyright protection altogether. But here the federal statutory scheme for generic drug competition provides that a generic competitor will

be required to use a pioneer drug's FDA-approved labeling in narrow, clearly specified circumstances. The submission of copyrighted materials in a pioneer drug's NDA cannot suffice to frustrate that scheme. Instead, submission of copyrighted materials must be deemed an implied, nonexclusive license limited to the use required by federal law. This understanding of the Hatch-Waxman Amendments cannot be understood to suggest a broad exception to the important guarantees of copyright protection; it merely recognizes that the particular statutory interaction here requires this harmonization.

A. Labeling Materials Are Not Typical Examples of Copyrighted Expression

Drug labeling materials exist largely because of FDA's rigorous approval process for new drugs. Labeling materials must accurately reflect the studies showing a drug product is safe and effective under certain conditions of use. FDA has the authority to reject an NDA because the labeling is insufficient. FDA could also require, as a condition of approval, the development of more engaging labeling, to ensure that consumers or health professionals read and understand the information. Those incidents of regulation emphasize that this is an unusual context for copyright concerns.

Typically, a copyrighted book or recording is developed for commercial exploitation, and the copyrighted material is sold by itself, in competition with other, different copyrighted material. Here, though, SmithKline developed the guide and audiotape to obtain FDA approval of Nicorette for over-the-counter sales; to our knowledge, these items are not sold on their own in competition with books or

motivational tapes marketed to help people quit smoking without the aid of drugs. See J.A. 444.

FDA has provided detailed regulatory requirements for labeling. See, e.g., 21 C.F.R. § 201.57 (format and content requirements for prescription drug product labeling). But, at least for some drugs (as this case demonstrates), a pioneer applicant can make substantial choices about many aspects of the proposed labeling. In the case of Nicorette, a key component of the application for over-the-counter sales was the inclusion of a user's guide and audiotape, both of which included information about what it takes to be a committed quitter and strategies for overcoming difficulties in the course of quitting smoking, as well as directions for use, warnings, and other elements of traditional labeling materials. See J.A. 17-52, 554-556. SmithKline could have sought approval based on proposed labeling that would not have included creative expressions in the user's guide and audiotape.

SmithKline sought FDA approval of Nicorette for over-the-counter sales in 1994, justifying that request with clinical trials in which Nicorette was accompanied by a user's guide and audiotape. J.A. 554-556. Those materials therefore constituted the conditions of use under which the drug could be deemed safe and effective. SmithKline's supplemental NDA accordingly was required to show that the proposed labeling accurately reflected those conditions for use. See 21 U.S.C. § 355(d)(1).

Notably, SmithKline faced a number of choices that undermine any copyright claim here. SmithKline might have chosen to use a less expressive guide either in its clinical studies or in its supplemental NDA. Indeed, SmithKline could have resorted

to the dry, factual language of traditional package inserts, which it asserts would not be copyrightable. SmithKline Br. 6. If SmithKline had chosen that path, it would have risked the possibility that FDA would have refused to approve Nicorette as safe and effective for over-the-counter sales. If SmithKline were primarily interested in protecting its intellectual property in the guide and the audiotape, it could have marketed the creative materials (separate from, and without reference to, Nicorette) as a self-help book -- a guide to quitting smoking, rather than as labeling for a drug subject to FDA approval.

B. FDA Can Accept, and Even Require, Expressive Material in Approved Labeling

SmithKline does not dispute that FDA can require the submission of particular labeling, even expressive or creative labeling. But the effect of SmithKline's legal theory here could effectively prevent FDA from approving effective generic competition for some pioneer drugs with unusual FDA-approved labeling. It could also effectively preclude FDA from requiring that certain labeling materials be included with a drug if those materials are subject to copyright protections.

If a pioneer manufacturer's submission of copyrighted material can effectively preclude a generic manufacturer from complying with same-labeling requirement of the Hatch-Waxman Amendments, the federal scheme for generic drug competition could easily be undermined. The ANDA process would be unavailable even after a pioneer drug's patent protection and market exclusivity expire. Copyright protection -- extending up to 125 years (see 17 U.S.C. § 302) -- could effectively vitiate

Congress's determination that generic competition should be quickly available on the expiration of a pioneer drug's period of market exclusivity (based on the 17-year protection afforded patented products, plus the extensions granted by Congress). There is no reason to conclude that Congress intended to allow such a serious subversion of the scheme for generic competition.

Nor would such an effect necessarily be limited to the unusual case. The Copyright Act makes plain that all original works of authorship are entitled to copyright protection. 17 U.S.C. § 102(a). The doctrine of merger directs that copyright does not attach when an idea can be expressed only in a limited number of ways. See, e.g., CCC Information Servs., Inc. v. Maclean Hunter Mkt. Reports, Inc., 44 F.3d 61, 68 (2d Cir. 1994), cert. denied, 516 U.S. 817 (1995); Kregos v. Associated Press, 937 F.2d 700, 705 (2d Cir. 1991). That principle might apply to some examples of traditional labeling, but there is nothing inherent in the definition of labeling that restricts it to bare-bones expressions of factual ideas. See 21 U.S.C.§ 321(m); 21 C.F.R. § 202.1(l)(2). Even fairly simple warnings and directions for use often could be expressed with different language. Indeed, Nicorette is not alone in claiming copyright protection for its labeling. See, e.g., Physicians' Desk Reference 641-646 (Cipro), 1061-1064 (Nutropin), 1258-1262 (Zantac), 1457-1464 (Theo-Dur), 1475-1477 (Dilaudid-HP), 2443-2448 (Zoloft) (53d ed. 1999).

Moreover, FDA might reasonably conclude that it cannot approve a drug as safe and effective for its intended uses unless it also requires particularly expressive or creative labeling subject to copyright protection. FDA needs to be able to inform

consumers and health professionals forcefully of the need for particular care due to a drug's unusually harmful side-effects or its efficacy only in a limited group of patients. As these issues arise, FDA is likely to continue to explore innovative ways of ensuring that appropriate warning information is communicated to patients, making it more likely that this crucial information will be expressed in ways traditionally susceptible to copyright.

C. The Hatch-Waxman Amendments Define the Expectations of a Pioneer Applicant That Submits Copyrighted Proposed Labeling for FDA Approval

When a pioneer drug manufacturer submits an NDA that includes copyrighted material as part of the proposed labeling, the manufacturer necessarily must expect that the labeling FDA ultimately approves will be used by a later generic competitor. That expectation precludes reliance on copyright law to prevent the later use provided for under federal law. Copyright law recognizes such an expectation as an implied, nonexclusive license. And, in analogous circumstances, the Supreme Court has held that a manufacturer cannot complain about the statutorily contemplated use of data it submitted to the Federal Government for approval of a pesticide. Both examples demonstrate that the Hatch-Waxman Amendments, while they do not abrogate copyright law, cannot be so easily frustrated as SmithKline claims.

1. Implied, Nonexclusive License

A license is authorization to engage in conduct that otherwise could be deemed copyright infringement. It is "leave to do a thing which the licensor would otherwise have a right to prevent." Western Elec. Co. v. Pacent Reproducer Corp., 42 F.2d 116,

118 (2d Cir.), cert. denied, 282 U.S. 873 (1930), quoted in I.A.E., Inc. v. Shaver, 74 F.3d 768, 775 n.7 (7th Cir. 1996). A copyright holder that grants a nonexclusive license retains its property interest in the copyright, and retains its full range of copyright remedies as against the world, but cannot sue the licensee for infringement so long as the licensee's use of the material conforms to the terms of the license. Effects Assocs., Inc. v. Cohen, 908 F.2d 555, 559 (9th Cir. 1990), cert. denied, 498 U.S. (1991). A nonexclusive license "is not expressly provided in the statutory text, but is negatively implied from the fact that a 'transfer of copyright ownership,' which by definition does not include nonexclusive licenses (see 17 U.S.C. § 101) must be by written instrument." 3 Nimmer on Copyright § 10.03[A] at 10-40.1 n. 19.

There is ample support in the case law for the fundamental principle that a copyright holder's conduct can create an implied, nonexclusive license. "A nonexclusive license can be granted orally or can be implied from the conduct of the parties." Korman v. HBC Florida, Inc., 182 F.3d 1291, 1293 (11th Cir. 1999); see also, e.g., Graham v. James, 144 F.3d 229, 235 (2d Cir. 1998) (quoting Nimmer on Copyright); Lulirama Ltd. v. Axcess Broadcast Servs., Inc. 128 F.3d 872, 880 (5th Cir. 1997) ("[w]hen the totality of the parties' conduct indicates an intent to grant such permission, the result is a legal nonexclusive license") (quoting Nimmer on Copyright). "[I]n the case of an implied nonexclusive license, * * * [t]he copyright owner simply permits the use of a copyrighted work in a particular manner." I.A.E., 74 F.3d at 775.

The terms of an implied, nonexclusive license are determined by reference to the circumstances surrounding the action that gave rise to the license. For example, the Ninth Circuit held that an implied copyright license was granted when material was submitted for inclusion in a book because, "without such a license, [the] contribution * * * would have been of minimal value." Oddo v. Ries, 743 F.2d 630, 634 (9th Cir. 1984), quoted in Effects, 908 F.2d at 558. Similarly, where an architect created drawings against a background expectation that they would be used on a project, and received $10,000 compensation in exchange, the Seventh Circuit held that there was an implied license for the use of the drawings to complete the project. I.A.E., 74 F.3d at 777. A copyright infringement claim remains available to redress a use that exceeds the scope of an implied license. See MacLean Assocs., Inc. v. Wm. M. Mercer-Meidinger-Hansen, Inc., 952 F.2d 769, 779 (3d Cir. 1991).

Here, a pioneer drug manufacturer that holds a copyright in particular materials must be understood to grant an implied, nonexclusive license when it submits those materials as proposed labeling for FDA approval in conjunction with an NDA. The terms of the implied license are defined by reference to the Hatch-Waxman Amendments, which require a generic drug to use the same labeling that was approved for the pioneer drug.

The doctrine of implied, nonexclusive license explains why the same-labeling mandate of the Hatch-Waxman Amendments is consistent with the Copyright Act. As applied to materials submitted to FDA for its approval in an NDA, the existence of an implied, nonexclusive license arises from the decision of a pioneer manufacturer

to seek approval for an NDA within the confines of federal law, including the Hatch-Waxman Amendments.

This Court has never categorically accepted or rejected the principle that a license could be implied by reference to federal law. In a case that was reversed on other grounds, this Court rejected a private party's argument that a license should be "implied in law." United Artists Television, Inc. v. Fortnightly Corp., 377 F.2d 872, 880-884 (2d Cir. 1967), rev'd, 392 U.S. 390 (1968); see also id. at 401-402 & n.32 (declining to address issue). The use of that term in the Fortnightly case was quite different from the circumstances presented here, however.

In Fortnightly, this Court concluded that the grant of a license for a television station to broadcast information did not imply a second license for a cable company to retransmit that information. 377 F.2d at 880-883. Neither the Court nor the relevant federal agency concluded that a comprehensive federal statutory scheme required the retransmission. Indeed, the Court noted that policy arguments concerning the best interpretation of federal law "must be made to Congress." Id. at 883; see also id. at 884 (concluding that Federal Communications Commission apparently had not taken the position that retransmission was necessary or that Communications Act would override copyright). Notably, the Supreme Court rejected the premise of that argument, concluding that the retransmission was not a performance of the copyrighted works (and therefore no license was necessary). 392 U.S. at 401 & n.32. In a later case involving similar issues, this Court declined to

reconsider the question whether a license might be implied in similar circumstances. See Columbia Broadcasting Sys. v. Teleprompter Corp., 476 F.2d 338 (2d Cir. 1973).

This is not a case in which an implied license for a second use must be extrapolated from conduct solely involving other private parties. Here, a federal statute (the Hatch-Waxman Amendments), as interpreted by the administering federal agency, directs that FDA-approved labeling will be used by a generic competitor. The copyright holder's voluntary request for official federal agency action (FDA approval of the proposed labeling materials for a pioneer drug) is the basis for the implied license. And the doctrine of implied license ultimately is merely a way of reconciling the dictates of two statutes, which otherwise might conflict.

Federal law plays only a background role in this context. As in any other circumstance, the finding of an implied license depends on a determination of the copyright holder's understanding and expectations concerning its copyrighted materials. Here, the Hatch-Waxman Amendments provide the governing legal rules that necessarily inform the copyright holder's expectations. SmithKline's decision to include copyrighted materials in its supplemental NDA, and its failure to challenge FDA's determination that those materials constitute labeling materials subject to FDA's approval, indicate that SmithKline knowingly and willingly acceded to Hatch-Waxman's terms -- including use of FDA-approved labeling by generic competitors -- in return for approval of Nicorette. In addition to the costs of the extensive studies required to demonstrate safety and efficacy, the price of approval included the grant

of a nonexclusive license to any generic manufacturer who obtains FDA approval of an ANDA based on Nicorette.

2. Ruckelshaus v. Monsanto Co.

This implied-license approach is also supported by the Supreme Court's resolution of a closely analogous issue concerning trade-secret protection of data submitted to the Environmental Protection Agency (EPA). See Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984). The Court there considered a challenge to a federal statute requiring a pesticide manufacturer to submit research and test data to support its application for a license to sell its product in the United States. Id. at 991-998. Monsanto asserted a property right in the confidentiality of the data it was required to submit, and the company complained that EPA's use and disclosure of those data amounted to an unconstitutional regulatory taking of private property.

The Supreme Court held, however, that "Monsanto was on notice of the manner in which EPA was authorized to use and disclose any data turned over to it." 467 U.S. at 1006. The Court noted that, "[i]n effect, the [statutory] provision instituted a mandatory data-licensing scheme." Id. at 992.[4] The Court emphasized that Monsanto voluntarily submitted its data with full awareness of the statutory scheme that provided for the use of those data by EPA and by competitors, and that

[4] The scheme at issue in Monsanto provided for negotiated or arbitrated compensation between the originator of the data and a later user. 467 U.S. at 992. Here, by contrast, Congress provided pioneer drug manufacturers with an extended period of patent protection, and market exclusivity after the expiration of applicable patents, which it concluded was ample compensation for the later generic competition provided for by the Hatch-Waxman Amendments.

the company could not later complain about the uses expressly contemplated by that statutory scheme. Id. at 1006-1007.

Although this is not a takings case, the Supreme Court's reasoning applies equally here. The Hatch-Waxman Amendments put a pioneer drug manufacturer on notice that, when it submits proposed labeling to FDA as part of its NDA, seeking approval to sell a new drug in the United States, the same FDA-approved labeling will be used by a generic competitor when the pioneer's patent and market exclusivity expires. As in Monsanto, a drug manufacturer is not compelled to give a license to its competitors; it does so as part of the cost of obtaining approval to sell its product in the United States. 467 U.S. at 1007 & n.11. A manufacturer cannot, however, take advantage of the benefits it obtains from obtaining approval for its product, then invoke some other legal theory to object to the price it was required to pay for that approval.

D. The Same-Labeling Requirement of the Hatch-Waxman Amendments Does No Violence to Copyright or Other Intellectual Property Law

Recognizing the objective expectations of a pioneer drug manufacturer, and understanding the submission of copyrighted materials for FDA approval as an implied license, do not put the copyright scheme at risk. The copyright holder does lose the ability to sue the licensee for infringement, but that is as a result of the interaction of the Hatch-Waxman Amendments with copyright law, which recognizes the existence of implied licenses. And the copyright holder retains the right to sue others who might infringe the copyright. For example, if a publisher copied the bulk

of SmithKline's user's guide and also produced an identical tape, then tried to sell the two of them directly to consumers as a guide to quitting smoking (without the Nicorette gum), such a reproduction would likely constitute copyright infringement, and nothing in the Hatch-Waxman Amendments would preclude an infringement suit in that circumstance.

Significantly, the copyright holder's objective expectation, which gives rise to its implied license, is narrow and defined by the contours of federal law. A pioneer manufacturer's submission of copyrighted materials as proposed labeling carries with it the understanding that a generic competitor whose ANDA is based on the pioneer drug will be entitled (indeed, required) to use the same labeling. But the license extends only to holders of approved ANDAs based on that pioneer drug. It does not allow third parties to use the materials. The copyright holder retains its exclusive rights under copyright law as against the rest of the world.

And the implied license allows only limited use of copyrighted labeling. A generic manufacturer is entitled to use the FDA-approved labeling only as labeling for the generic drug, and only subject to FDA approval. Thus, approval of an ANDA does not give a generic drug manufacturer authorization to use the pioneer's copyrighted labeling for other purposes. For example, the ANDA holder would not be entitled to use the copyrighted material in another format, such as a self-contained guide to quitting smoking apart from the generic drug.

Finally, although the implied license encompasses all materials submitted as proposed labeling and approved by FDA, it does not authorize use of a pioneer's

name, trademarks, or trade dress. Proposed labeling frequently includes a pioneer drug's proprietary (brand) name, which often is trademarked. See, e.g., 21 C.F.R. §§ 201.10, 201.57(a)(1)(i), 201.61(b). FDA also requires that an NDA applicant submit the actual packaging for the drug as part of the proposed labeling. 21 C.F.R. § 314.50(e)(2)(ii). That packaging may include slogans or logos, as well as trade dress characteristics. Although all of those elements of proposed labeling are reviewed by FDA, the Hatch-Waxman Amendments do not require (indeed, do not permit) a generic drug to duplicate them because to do so would constitute misbranding.

The same-labeling requirement does not override the misbranding provision of the FD&C Act, which prohibits labeling that is "false or misleading in any particular." 21 U.S.C. § 352(a). FDA has, by regulation, concluded that a drug is misbranded if its label includes a "false or misleading representation with respect to another drug." 21 C.F.R. § 201.6(a). And a label must clearly identify the product it relates to. See id. § 201.50 (statement of identity for prescription drugs); id. § 201.57(a)(1)(i) (proprietary name and established name of prescription drug required in description section); id. § 201.61 (statement of identity for over-the-counter drugs). Thus, it would be a violation of the FD&C Act, as well as FDA regulations, for a manufacturer to attempt to pass off a generic drug as a brand-name product by using the name or other distinguishing characteristics of the pioneer.

POINT III

THE FACTS OF THIS CASE DO NOT DICTATE A RESULT OUTSIDE THE SCHEME OF THE HATCH-WAXMAN AMENDMENTS

The foregoing analysis establishes that a pioneer drug manufacturer must expect that a later generic drug will be required to use the same labeling that was approved for the pioneer drug, subject only to the narrow exceptions set forth in FDA's regulations and to the misbranding prohibition in the FD&C Act. Whether seen as an implied, nonexclusive license under copyright law, or as an expectation based on the federal legal scheme (as in Monsanto), the result is the same: There can be no copyright infringement claim for the use expressly contemplated by the Hatch-Waxman Amendments.

SmithKline does not dispute that at least some of its labeling materials are properly subject to the same-labeling requirement. SmithKline Br. 6. Instead, much of SmithKline's claim is actually a disagreement with FDA's application of that requirement to portions of the specific materials at issue here -- the user's guide and audiotape. SmithKline contends that some or all of those materials are not properly within the scope of the same-labeling requirement, and that FDA erred when it sought to identify some portions of the labeling materials that could be changed by Watson. Id. at 43-46. That claim is not properly before the Court in this case.

A. The Same-Labeling Requirement Applies to All Labeling Submitted in an NDA for FDA Approval

The statutory and regulatory definitions of labeling are quite broad. 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(l)(2); see also Kordel v. United States, 335 U.S. 345,

349-350 (1948) (interpreting definition broadly). Advertisements, promotional materials, coupons, and the like, as well as packaging materials, package inserts, and any other instructions for use, warnings, indications, dosage and similar information, all come within the terms of the FD&C Act's restrictions on labeling. It is important to note, however, that not all of those materials are subject to the same-labeling requirement of the Hatch-Waxman Amendments.

The Hatch-Waxman Amendments require a generic to duplicate only "the labeling approved for the [pioneer] drug." 21 U.S.C. § 355(j)(2)(A)(v) (emphasis added). The statute's limitation to FDA-approved labeling refers to the NDA process by which a pioneer drug obtains pre-market approval. An NDA must include the text of the proposed labeling being submitted for FDA review and approval. See 21 C.F.R. § 314.50(c)(2)(i). The text of the proposed labeling must be annotated to refer to the studies or other data supporting each statement. Id. In addition, upon request from FDA, an NDA applicant must provide samples of the "finished market package" and "the label and all labeling for the drug product." Id. § 314.50(e)(1)(ii), (e)(2)(ii).

The proposed labeling submitted for FDA approval in an NDA must conform to extensive, detailed regulatory requirements. See 21 C.F.R. Pt. 201. As a general matter, the labeling of every drug must include the name and other identifying information of the manufacturer, packer, or distributor. Id. § 201.1. Labeling must also include a statement of the drug's ingredients, which include any substance in the drug. Id. § 201.10. Finally, most non-prescription drugs must include "adequate directions for use" -- "directions under which the layman can use a drug safely and

for the purposes for which it is intended." Id. § 201.5; see also id. § 201.100 (exemption for prescription drugs); id. §§ 201.105 - 201.125 (other exemptions). These general requirements implement the statutory provisions that describe when a drug is misbranded. 21 U.S.C. § 352.

FDA regulations also specify the format and content of proposed labeling. See 21 C.F.R. § 201.57 (prescription drugs); id. § 201.66 (over-the-counter drugs). For prescription drugs, those regulations specify that labeling must include the following information about the drug: (1) description, including names and ingredients; (2) clinical pharmacology (how the drug acts on the human body); (3) indications and usage; (4) contraindications; (5) warnings; (6) precautions; (7) adverse reactions; (8) drug abuse and dependence; (9) dosage and administration; and (10) dosage form (how the drug is supplied). Id. § 201.57(a)-(k).[5]

In many cases, the proposed labeling included in an NDA will simply follow the specific requirements of the regulations, and may incorporate little or no creative or expressive content. Nothing about the FDA regulations, however, prohibits an

[5] Similar information, in an even more detailed format, is also required for over-the-counter drugs, whose labeling must detail (1) active ingredients; (2) purposes (pharmacological categories or principal intended actions); (3) uses, or indications; (4) warnings; (5) directions for use; (6) other information required by FDA; and (7) inactive ingredients. 21 C.F.R. § 201.66(c)(2)-(8). That provision became effective on April 16, 1999. See 64 Fed. Reg. 13286 (1999). Before that date, FDA regulations did not provide detailed requirements for over-the-counter drug labeling generally, although monographs for particular categories of drugs typically detailed the required labeling. For over-the-counter drugs that were not the subject of monographs, including Nicorette (after it was approved for over-the-counter sale), the required labeling was set forth in the NDA, and was reviewed and approved by FDA in that context.

NDA applicant from proposing labeling that is creative or expressive. An applicant may choose to include additional, or more user-friendly, information in the proposed labeling. Reasons for doing so could include the need to ensure that consumers or health professionals adequately understand important information about a drug's uses or hazards. Or FDA could request or require that an applicant provide particular labeling material. Whatever the reason, an applicant submits proposed labeling to FDA with the expectation that it will become the approved labeling that must be included with the drug.

When FDA approves an NDA, the final labeling that is part of that application becomes the approved labeling. It can be changed only if FDA approves the change. See 57 Fed. Reg. at 17961. Some changes are allowed to take effect upon notice to FDA, and others can take effect with subsequent notice in an annual report of changes to the drug. See 21 C.F.R. § 314.70.

The broad statutory and regulatory definitions of labeling subsume additional materials, including advertisements and promotional materials. Those elements are not required to be included in an NDA, and accordingly do not become part of the approved labeling when an NDA is approved. Many such materials are submitted to FDA for its review (in part to minimize the risk of enforcement proceedings), but neither review nor approval of promotional materials is generally required by the FD&C Act or FDA's regulations. Because promotional materials are not required to be approved as part of an NDA, they are not within the same-labeling requirement of the Hatch-Waxman Amendments.

B. The User's Guide and Audiotape at Issue in This Case Were Submitted to, and Approved by, FDA

Nicorette was approved by FDA as a nicotine replacement therapy, a form of smoking-cessation aid. When originally approved by FDA in January 1984 (J.A. 116), Nicorette was available only by prescription. See 21 U.S.C. § 353(b)(1) (prescription-only drugs). At that time, in addition to patent protection, Nicorette received an additional ten-year period of market exclusivity conferred by the Hatch-Waxman Amendments. See, e.g., Mead Johnson, 838 F.2d at 1333.

In 1984, FDA concluded that Nicorette was safe and effective for its intended use at that time without extensive additional labeling materials. As with any prescription drug, physicians were expected to provide their patients with the instructions for use and warnings. But in the case of Nicorette, physicians were also expected to provide any necessary behavioral support.

In 1994, SmithKline submitted a supplemental NDA in a bid for approval to switch Nicorette from a prescription-only drug to over-the-counter status, so that it would be available directly to consumers. J.A. 555-556. Nicorette received three additional years of market exclusivity under the Hatch-Waxman Amendments as a result of its switch to over-the-counter status. As part of its application for approval of that switch, SmithKline included the user's guide and audiotape. One purpose of the user's guide and audiotape was to provide some of the behavioral support that a physician would have provided when the drug was available only by prescription. But the user's guide and audiotape also included information concerning detailed

directions for use, warnings, indications, contraindications, and other elements traditionally included as proposed labeling in an NDA. See J.A. 17-52. The supplemental NDA was required to show that Nicorette was safe and effective for use without the supervision of a physician. See 21 U.S.C. § 353(b)(1).

As part of its supplemental NDA, SmithKline included the results of studies designed to show that Nicorette is safe and effective for its intended use as part of a comprehensive smoking-cessation program. See J.A. 554-556. In clinical studies, Nicorette was provided to consumers along with a user's guide and audiotape containing behavioral support information as well as other information, including directions for use and warnings. The proposed labeling submitted to FDA included a user's guide and audiotape that contained similar, but not identical, information. To support its application, which sought approval of labeling that differed from the conditions of the supporting clinical studies, SmithKline was required to demonstrate that the proposed labeling accurately and sufficiently described the conditions under which the drug could be used safely and effectively. See 21 U.S.C. § 355(d)(1).

FDA carefully reviewed SmithKline's supplemental NDA, and required certain changes to be made in the proposed labeling. J.A. 554-559. After FDA was satisfied with the proposed labeling, as well as other aspects of the application, it issued an approval letter authorizing the over-the-counter sale of Nicorette, along with the approved labeling. J.A. 560. SmithKline does not dispute that FDA treated the user's guide and audiotape as proposed labeling during the agency's consideration and

approval of the supplemental NDA and that those materials are FDA-approved labeling.

In light of those events, SmithKline cannot (and does not appear to) claim that the user's guide and audiotape are not part of the approved labeling. Given the statutory and regulatory language, and the circumstances under which its NDA was approved, SmithKline plainly was aware that the user's guide and audiotape were subject to the same-labeling requirement. Indeed, in its supplemental NDA, SmithKline demonstrated that Nicorette is safe and effective under the conditions of use as described in the labeling, including the user's guide and audiotape; FDA has not had occasion to consider whether Nicorette would be equally safe and effective with different labeling.

C. SmithKline has Not Proposed, and FDA Has Not Approved, Different Labeling for Nicorette

This copyright infringement action is not a proper vehicle for SmithKline's complaints that FDA's actions are "unreasonable and indefensible." SmithKline Br. 44. Neither FDA nor the United States is a party to this case, which is styled as a copyright infringement claim against a private party. Nor would there be any basis for seeking relief against FDA in this case; there is no claim that the United States itself has infringed any copyright (nor could there be). The district court therefore correctly recognized that it could not direct FDA to take any action. J.A. 627 n.3. Nevertheless, SmithKline continues to assert that it is entitled to prevail on its copyright infringement claim on the ground that FDA's actions concerning Watson's

ANDA are indefensible. See SmithKline Br. 43-46. This proceeding is not a proper forum for an inquiry into FDA's policies or decisions, and this Court should reject SmithKline's collateral attack on agency action.

During the proceedings below, FDA responded to particular inquiries from the district court concerning the agency's policies and the legal and regulatory basis for its actions on Watson's application. In light of confusion in the district court proceedings, this brief is intended to clarify the Government's position. After the district court's December 22 ruling, FDA and other interested offices within the Federal Government consulted. As a result, FDA adheres to its original view -- that a generic drug's labeling must duplicate exactly the labeling approved for its pioneer counterpart (except for the specific exceptions outlined in FDA's regulations). That view is consistent with the statutory language and FDA regulations, and with FDA's March 1999 approval of Watson's ANDA with labeling that did not differ from Nicorette's approved labeling, except as required by FDA's regulations. FDA intends to take any necessary steps to bring its treatment of Watson's ANDA into conformity with that view.

As discussed above, the Hatch-Waxman Amendments, as interpreted by FDA, do not allow a generic drug's labeling to vary from "the labeling approved for the [pioneer] drug." 21 U.S.C. § 355(j)(2)(A)(v). The FDA-approved labeling includes all materials (within the broad statutory and regulatory definition of "labeling") that an applicant submits to FDA for approval of an NDA. An NDA approved on the basis of labeling that includes behavioral support materials is no different.

Another manufacturer could seek approval, in an NDA, of a competing product accompanied by different labeling. But the Hatch-Waxman Amendments, as interpreted by FDA, do not allow such variation in an ANDA, which must include labeling that is "the same as" the pioneer drug's FDA-approved labeling. 21 U.S.C. § 355(j)(2)(A)(v). The ANDA process established by the Hatch-Waxman Amendments simply affords FDA no way of knowing whether a different expression, which assertedly contains the same ideas, in fact renders the drug product equally safe and effective for the same conditions of use. See also supra n.4.

None of FDA's statements in the district court would support the result that SmithKline now urges -- a wholesale exception to the same-labeling requirement. As we have explained, SmithKline cannot use copyright law to prevent the use of its FDA-approved labeling by a generic competitor, as provided for by the Hatch-Waxman Amendments. Because the approved labeling for Nicorette plainly included the entire user's guide and audiotape, there is no basis for SmithKline to seek any changes in this copyright infringement case.

If SmithKline seeks to prevent copying of some elements of its user's guide and audiotape, it has the option of seeking FDA approval of amended labeling. For example, SmithKline could file a supplemental NDA with information sufficient to show that Nicorette is safe and effective for its intended uses with less creative labeling materials. SmithKline could attempt to show that a more traditional package insert -- with detailed information about such matters as directions for use, indications, warnings, and contraindications -- is sufficient as required labeling.

If such an effort were to succeed, the amended labeling would no longer include the user's guide and audiotape; those materials would not be part of the FDA-approved labeling for Nicorette and would therefore no longer be subject to the same-labeling requirement in the Hatch-Waxman Amendments. Watson would be required to amend its labeling to conform to the current approved labeling for its pioneer counterpart. And SmithKline would thereby have prevented the use of its copyrighted materials.

Such a change would require FDA approval, and with good reason. Changes to approved labeling have the clear potential to affect the safety and efficacy of a drug. FDA's approval of SmithKline's supplemental NDA for over-the-counter sales of Nicorette was based on the distribution of the drug with the approved labeling (including the user's guide and audiotape). If SmithKline now believes that Nicorette can be approved without those materials, or with similar information in a less creative presentation, it must demonstrate to FDA that the drug is safe and effective with the newly proposed labeling.

Depending on the contents of such a supplemental application, FDA might conclude that it cannot approve Nicorette without behavioral support materials. Such a determination would be well within the agency's authority, if SmithKline were unable to demonstrate that Nicorette is safe and effective without those materials. In that circumstance, SmithKline could propose amended behavioral support materials that do not include the creative content SmithKline seeks protection for in this case.

If FDA were to conclude that Nicorette's labeling would be adequate with only minimal behavioral support materials, SmithKline might also propose to use more expressive behavioral support materials -- perhaps including some of the content now in the user's guide and audiotape -- as promotional materials, which do not constitute approved labeling and accordingly are not subject to the same-labeling requirement. If those materials were truthful and non-misleading, nothing in the FD&C Act or FDA's regulations would prevent SmithKline from distributing them.

But it would in any event be inconsistent with the Hatch-Waxman Amendments for SmithKline to imply that its product has a therapeutic difference from its generic competitor. By definition, there is no basis for distinguishing the two on such grounds, because FDA has determined that they are therapeutically equivalent and that their labeling must be the same to reflect that equivalence.

CONCLUSION

For the foregoing reasons, the decision of the district court should be affirmed.

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