



MERCK & CO. v. KESSLER

903 F. Supp. 964 (1995) | Cited 0 times | E.D. Virginia | October 16, 1995

MEMORANDUM OPINION

Effective June 8, 1995, as a result of the enactment of the Uruguay Round Agreements Act (URAA), the terms of patents formerly seventeen years from the date the patent issued, was changed as follows:

Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

35 U.S.C. § 154(a)(2).

A transitional provision provided as follows:

The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (1), or 17 years from grant, subject to any terminal disclaimers.

35 U.S.C. § 154(c)(1).

The issue in these cases is whether extension or restoration rights of patent terms which have been allowed pursuant to 35 U.S.C. § 156 (The Waxman-Hatch Act) for a time equal to the regulatory review period (two years insofar as these cases are concerned) can be used to extend the twenty year period as to patents which are in force on June 8, 1995. ¹ In other words, can a holder of a patent in force on June 8, 1995, add a previously granted patent restoration period to a twenty year term in determining when the patent expires.

On June 7, 1995, the Patent and Trademark Office (PTO) published a "Final Determination" which in effect ruled that the holder of such a patent must choose between a term of seventeen years from grant of the patent plus a restoration period, or a term of twenty years from filing without the restoration period.



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The Food and Drug Administration (FDA), charged with publication of patent expiration dates submitted by holders of patents in force on June 8, 1995, has refused to publish expiration dates calculated in a manner inconsistent with the ruling of the PTO.

The plaintiffs in these actions are holders of patents in force on June 8, 1995, which have previously been accorded restoration rights and who have been refused publication of their submitted expiration dates by the FDA because of the PTO ruling. The plaintiffs challenge the actions of the FDA and the PTO and seek declaratory judgments that the actions are unlawful, that their patents expire only after twenty years, plus the previously granted restoration right, and injunctive relief in the form of a direction to the FDA to publish and a withdrawal by the PTO of the Final Determination ruling.

The actions are before the court on the plaintiffs' motions for summary judgment. The government has responded with a motion to dismiss, which is in reality a cross motion for summary judgment. Permitted to intervene and participate in the argument in support of the government's position was the Generic Pharmaceutical Industry Association (GPIA). This is a national trade association whose members include the majority of the manufacturers of generic pharmaceuticals, who obviously have an interest in when patents on pharmaceuticals, the types of patents at issue in this case, expire.

* * *

It is conceded that any patent applied for after June 8, 1995, would be for twenty years and would have the benefit of any extension available to it under 35 U.S.C. § 156. The URAA is silent as to the application of regulatory review extensions to the twenty year term. It seems apparent to the court, however, that the URAA's change of the term length was to do no more than bring United States patent law into closer harmony with the laws of other developed nations. Its transitional provision, by providing that the patent term is to apply to previously issued patents, is further indication that no differentiation in restoration rights for patents with the later life was intended. Many statutory enactments draw lines, and some form of prejudice or benefit can accrue depending on which side of the line a party ends up on after the enactment. But the disparate impact on those patent applicants who precede June 8, 1995, and those who follow, which would result from the PTO's Final Determination, is inconsistent with the apparent even-handedness intended by the URAA. To draw the inference that the URAA was intended to or did operate to strip from patents in force on June 8, 1995, the carefully drafted regulatory review extensions merely because that act lengthened the patent term from seventeen to twenty years, is not warranted.

The government places its primary argument on the use of the term "original expiration date" as used in The Hatch-Waxman Act. 35 U.S.C. § 156(a), in providing for extensions, is worded as follows:

The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original



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expiration date of the patent if.... (Emphasis supplied.)

The government argues that this can only mean the original expiration date from a patent whose term is seventeen years. This is too narrow a construction. The URAA in effect extended the original expiration date to twenty years from the date of application. It effected a change in the "term" as used in § 156(a) and § 156(c).

Nor is the court persuaded by the asserted complicated recalculation involved in the sixty day provision and fourteen year limitation set forth in 35 U.S.C. § 156(d)(1) and § 156(c)(3), respectively.

The court is likewise unpersuaded by the argument, principally made by the intervenor, that permitting the two year regulatory review extension to be added to the twenty year term for the patents at issue in this case is somehow a second extension which is prohibited by Waxman-Hatch. The only extension which results from adding the two years to the twenty years is the extension applied to the terms of all patents by the URAA. This was no more a windfall to the plaintiffs than the windfall which benefitted many patent holders when the seventeen year term of patents was extended to twenty years.

A substantial portion of the defendants' brief is directed to the deference owed an agency's determination. In the court's view, this is not an issue in the case. Resolution of what the court perceives to be the issues involved here, is a straightforward matter of statutory interpretation.

The declaratory and injunctive relief requested by the plaintiffs will be granted,² and the court will declare the eleven patents in issue to have the expiration dates dictated by allowing the previously granted extension to be added to the twenty year term.

Albert V. Bryan, Jr.

United States District Judge

Alexandria, Virginia

October 16th, 1995

ORDER

Upon consideration of the arguments and submissions of the parties and for the reasons set forth in the Memorandum Opinion this day filed, it is hereby ADJUDGED, ORDERED and DECLARED that:

1. These actions are consolidated.



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2. The motion of Generic Pharmaceutical Industry Association (GPIA) to intervene is granted.
3. The motion of the plaintiffs for summary judgment are granted.
4. The motion of David A. Kessler, M.D., Commissioner of Food and Drug (FDA), and Bruce A. Lehman, Commissioner of Patents and Trademarks (PTO), and the intervenor to dismiss and for summary judgment are denied.
5. The Final Determination of the PTO published in the Federal Register at 60 Fed Reg. 30069 on June 7, 1995, is invalid and unenforceable. 6. The expiration dates for the patents at issue in this action are as follows: Patent No. Holder Exp. Date (w/20 +2) 4,001,323 Bracco 11/24/974,282,233 Schering 6/19/024,283,408 Merck 10/15/004,146,719 Merck 2/16/004,231,938 Merck 6/15/014,316,839 Roche 10/10/044,278,663 Roche 1/30/034,078,071 Syntex 7/28/974,089,969 Syntex 7/14/984,355,032 Syntex 6/23/033,985,758 Syntex 2/15/96
7. For patents entitled to a term of the greater of twenty years from patent filing or seventeen years from grant, under 35 U.S.C. § 154(c)(1), periods of restoration of patent life that have been granted, or that will be granted under 35 U.S.C. § 156, are added to that term.
8. The refusal of the FDA to publish the above expiration dates as submitted by the plaintiffs is invalid and unlawful.
9. The FDA shall withdraw its Notice declining to publish the above expiration dates in the "Orange Book" as proper expiration dates submitted by the plaintiff, and shall publish those dates in the Orange Book.
10. The Final Determination of the PTO, mentioned above, shall be withdrawn by the PTO.
11. The FDA is prohibited from approving any abbreviated new drug applications, abbreviated new animal drug application or applications filed under 21 U.S.C. § 355(b)(2) that do not take into account the expiration dates of patents as determined by this order.

Albert V. Bryan, Jr.

United States District Judge

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1. Some of the patents at issue in these cases had not expired as of June 8, 1995, because the seventeen years had not run,



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and some of the patents at issue were in force as of June 8, 1995, only because they had previously been granted regulatory review extensions.

2. The patents at issue in this action all have had extensions previously granted. Because the rationale of the court's ruling applies to extensions available in the future, the declaratory and injunctive relief applies to patents in force on June 8, 1995, but which may be entitled to extensions in the future.

