(2) the time and place of and person responsible for the statement; (3) the content and manner in which the statements misled the Plaintiffs; and (4) what the Defendants gained by the alleged fraud. *Brooks*, 116 F.3d at 1380–81. In *Brooks*, we concluded that the complaint alleging a RICO claim did not meet the Rule 9(b) particularity standard[11] because it was devoid of specific allegations with respect to each defendant; the plaintiffs lumped together all of the defendants in their allegations of fraud. *Id.* at 1381. "[I]n a case involving multiple defendants . . . the complaint should inform each defendant of the nature of his alleged participation in the fraud." *Id.*

[10] After a thorough review of Ambrosia's Fourth Amended Complaint, we conclude that Ambrosia failed to plead its civil RICO claims against each defendant with the required level of specificity.[12]

CONCLUSION

Accordingly, we REVERSE the district court with respect to Ambrosia's state law claims. We find that subject matter jurisdiction exists, and, therefore we REMAND the state law claims for further proceedings. With respect to the federal civil RICO claims, we AFFIRM the district court's dismissal of these claims.

11. The pleading requirements of FED.R.CIV.P. 9(b) are codified in the Local Rules of the United States District Court for the Southern District of Florida. *See* S.D. Fla. L.R. 12.1.

12. For example in Count XXV, Ambrosia inaccurately states that Defendant Pages and Isla Verde Beach Hotel & Casino, S.E. defrauded Ambrosia as described in paragraphs 24–31 and 31–41, when in fact these paragraphs only discuss Strollo and Malizia's actions. Count XXV does not discuss the nature of each defendant's participation in the scheme, nor does Count XXV discuss each alleged statement, document, or misrepresentation made with the proper level of precision. Furthermore, Count XXV generally states that Ambrosia relied upon each of the material misrepresentations without specifying the content or manner in which the statements misled Ambrosia. Count XXVI mirrors Count XXV and the 9(b) issues equally apply to Count XXVI.

MERCK & CO., INC., Plaintiff–Appellee,

v.

HI–TECH PHARMACAL CO., INC., Defendant–Appellant.

No. 2006–1401.

United States Court of Appeals, Federal Circuit.

March 29, 2007.

Rehearing and Rehearing En Banc Denied June 4, 2007.

Background: Owner of patent for drug used to treat glaucoma filed infringement action against proposed manufacturer of generic version of drug. The United States District Court for the District of New Jersey, Mary L. Cooper, J., denied manufacturer's motion to dismiss, granted patentee's motion for judgment on the pleadings, and enjoined manufacturer from commercializing drug until the end of the patent term extension. Manufacturer appealed.

Holding: The Court of Appeals, Linn, Circuit Judge, held that patent term extension under the Drug Price Competition and Patent Term Restoration Act could be applied to patent subject to a terminal disclaimer.

Affirmed.

1. Courts ⚿96(7)

As with motions to dismiss for failure to state a claim, the question of whether a

motion for judgment on the pleadings was properly granted is a purely procedural question not pertaining to patent law, to which the Federal Circuit applies the rule of the regional circuit. Fed.Rules Civ. Proc.Rules 12(b)(6), 12(c), 28 U.S.C.A.

2. Federal Courts ⚿754.1

The Court of Appeals exercises plenary review over a question of statutory construction.

3. Statutes ⚿227

Use of the word "shall" in a statute generally denotes the imperative.

4. Patents ⚿133

Use of the word "shall" in the Drug Price Competition and Patent Term Restoration Act (the Hatch–Waxman Act) indicates that if the enumerated list of requirements is met, the patent term is entitled to be extended. 35 U.S.C.A. § 156(a).

5. Patents ⚿133

The express prohibition against a term adjustment regarding Patent and Trademark Office (PTO) delays, the absence of any such prohibition regarding patent term extension under the Drug Price Competition and Patent Term Restoration Act (the Hatch–Waxman Act), and the statutory mandate that the patent term shall be extended if the requirements enumerated in that section are met, support the conclusion that a patent term extension under the Act is not foreclosed by a terminal disclaimer. 35 U.S.C.A. §§ 156, 253.

6. Patents ⚿133

Patent term extension under the Drug Price Competition and Patent Term Restoration Act (the Hatch–Waxman Act) could be applied to a patent for drug used to treat glaucoma that was subject to a terminal disclaimer, filed to overcome an obviousness-type double-patenting rejection. 35 U.S.C.A. §§ 156, 253.

Patents ⚿328(2)

4,677,115, 4,797,413. Cited.

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William L. Mentlik, Lerner, David, Littenberg, Krumholz & Mentlik, LLP, of Westfield, New Jersey, argued for defendant-appellant. With him on the brief was Roy H. Wepner. Of counsel on the brief was Alfred B. Engelberg, of Palm Beach, Florida.

Before LINN, Circuit Judge, FRIEDMAN and PLAGER, Senior Circuit Judges.

LINN, Circuit Judge.

This case presents the question of whether a patent term extension under the Hatch–Waxman Act, 35 U.S.C. § 156, may be applied to a patent subject to a terminal disclaimer under 35 U.S.C. § 253, filed to overcome an obviousness-type double-patenting rejection. Because the language of § 156 is unambiguous and fulfills a purpose unrelated to and not in conflict with that of § 253, we hold that a Hatch–Waxman term extension may be so applied.

I. BACKGROUND

Merck & Co, Inc. ("Merck") is the inventor of TRUSOPT®, a drug used to treat glaucoma. On June 26, 1987, Merck filed a patent application covering certain carbonic anhydrase inhibitors, including dorzolamide, which is the active ingredient in TRUSOPT®. That patent application eventually issued as United States Patent No. 4,797,413 (the "'413 patent"). During prosecution of the '413 patent, the examin-

er rejected all claims on the ground of obviousness-type double patenting over the claims of an earlier patent also owned by Merck. That patent, U.S. Patent No. 4,677,115 (the "'115 patent"), issued on June 30, 1987. To overcome this rejection, Merck filed a terminal disclaimer under 35 U.S.C. § 253. The terminal disclaimer disavowed any term of the '413 patent that would extend beyond June 30, 2004, the original term of the '115 patent (17 years from its date of issue). The filing of the terminal disclaimer was accepted by the Examiner as overcoming the double-patenting rejection and, on January 10, 1989, the '413 patent was granted.

In 1994, the Uruguay Round Agreements Act (URAA) was enacted. That act "harmonize[d] the term provision of United States patent law with that of our leading trading partners which grant a patent term of 20 years from the date of filing of the patent application." *Merck & Co. v. Kessler,* 80 F.3d 1543, 1547 (Fed.Cir.1996). Under the URAA, the term of a patent then in force was amended to the greater of 20 years from its earliest effective filing date or 17 years from its date of issue. *See* 35 U.S.C. § 154(a)(2), (c)(1). The '115 patent was subject to the URAA, and consequently, its expiration date was reset by operation of law to December 12, 2004 (twenty years from the filing date of the '115 patent). Because the terminal disclaimer linked the expiration date of the '413 patent to the term of the '115 patent, the expiration date of the '413 patent likewise was reset to December 12, 2004.

Merck sought and received approval from the United States Food & Drug Administration ("FDA") to market TRUSOPT®. As part of the approval process, Merck was required to submit information to the FDA on any patent that claims the approved drug or method of using the drug, and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1). The FDA publishes patent information on approved drug products in the "Orange Book," a register that provides notice of patents covering name brand drugs. The Orange Book shows that the '413 patent covers TRUSOPT®. *See* Approved Drug Products with Therapeutic Equivalence Evaluation (the "Orange Book").

On March 20, 1997, at the request of Merck and pursuant to 35 U.S.C. § 156, the Patent and Trademark Office (the "PTO") extended the term of the '413 patent based on the period of regulatory review undertaken by the FDA of Merck's TRUSOPT® drug. The PTO granted the patent term extension for a period of 1233 days and calculated the extension to run from the effective date of the terminal disclaimer, i.e., December 12, 2004. Based on the patent term extension, the expiration date of the '413 patent thus became April 28, 2008.

The patent infringement dispute at issue here began in August 2005, when Hi–Tech Pharmacal Co., Inc. ("High–Tech") filed with the FDA Abbreviated New Drug Application Nos. 77–846 and 77–847 ("ANDA Nos. 77–846 and 77–847") for a generic version of a drug containing the active ingredient dorzolamide and used in drops for the treatment of ocular hypertension. The Federal Food, Drug, and Cosmetic Act requires that an ANDA application contain a certification for each patent listed in the Orange Book for the brand-name drug. This certification must state one of the following: (i) that the required patent information relating to such patent has not been filed; (ii) that such patent has expired; (iii) that the patent will expire on a particular date; or (iv) that such patent is invalid or will not be infringed by the drug for which approval is being sought. 21 U.S.C. § 355(b)(2)(A). The ANDA appli-

cant who certifies, under paragraph iv, that a listed patent is invalid or not infringed, must, among other things, notify the patent owner that it has filed an ANDA containing a patent challenge. 21 U.S.C. § 355(b)(3). Pursuant to these rules, Hi–Tech sent a paragraph iv patent certification notice to Merck, stating that Hi–Tech's generic eye-drops do not infringe the '413 patent. In response, on January 18, 2006, Merck sued Hi–Tech for infringement pursuant to 35 U.S.C. § 271(c)(2)(A), alleging that the filing of ANDA Nos. 77–846 and 77–847 was an act of infringement. Hi–Tech answered that the patent had expired on December 12, 2004 and was not enforceable after that date.

On March 1, 2006, Hi–Tech filed a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) on the ground that while its products were covered by the claims of the '413 patent, the terminal disclaimer foreclosed the patent term extension and the '413 patent therefore expired on December 12, 2004. On April 3, 2006, Merck filed a cross-motion for judgment on the pleadings on the ground that the terminal disclaimer did not foreclose the Hatch–Waxman term extension, arguing that the reasoning of *King Pharmaceuticals, Inc. v. Teva Pharmaceuticals, Inc.*, 409 F.Supp.2d 609 (D.N.J.2006), should apply.

On April 25, 2006, the district court entered a final judgment, denying Hi–Tech's motion to dismiss and granting Merck's motion for judgment on the pleadings. *See Merck & Co. v. Hi–Tech Pharmacal Co.*, Nos. 06–266 and 06–268 (D.N.J. April 25, 2006). The District Court adopted the reasoning of *King Pharmaceuticals* and enjoined Hi–Tech from commercializing the drug claimed in the '413 patent until the end of the patent term extension, i.e., until April 28, 2008. *See Merck*, Nos. 06–266 and 06–268, slip op. at 2. Hi–Tech timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

[1, 2] As with Rule 12(b)(6) motions, the question of whether a motion for judgment on the pleadings was properly granted is a purely procedural question not pertaining to patent law, to which this court applies the rule of the regional circuit. *See C & F Packing Co. v. IBP, Inc.*, 224 F.3d 1296, 1306 (Fed.Cir.2000). The Third Circuit exercises plenary review of such Rule 12(c) motions using the same standard as the district court. *E.g., CoreStates Bank, N.A. v. Huls Am., Inc.*, 176 F.3d 187, 193 (3d Cir.1999). The only debated question in this case—the scope of 35 U.S.C. § 156—is a question of statutory construction, over which we also exercise plenary review. *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1314 (Fed. Cir.2005).

B. Analysis

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch–Waxman Act"), 98 Stat. 1585, which amended the Federal Food, Drug, and Cosmetic Act and the patent laws. The issue in this case concerns the proper interpretation of a portion of § 201 of the Hatch–Waxman Act, codified at 35 U.S.C. § 156.

This provision established a patent term extension for patents relating to certain products subject to regulatory delays that could not be marketed prior to regulatory approval. Section 156 provides an extension of up to five years if certain conditions are met. The conditions are set forth in the five numbered sub-paragraphs of § 156(a).

35 U.S.C. § 156 provides, in relevant part:

> (a) 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 expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if
>
> (1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;
>
> (2) the term of the patent has never been extended under subsection (e)(1) of this section;
>
> (3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);
>
> (3) the product has been subject to a regulatory review period before its commercial marketing or use;
>
> (5)(A) except as provided in subparagraph (B) or (C) [not relevant in this case], the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.

35 U.S.C. § 156(a) (emphasis added).

Hi–Tech does not challenge that the '413 patent meets each of the enumerated conditions of § 156 but rather contends that as a condition for the lifting of the double-patenting rejection and thus the grant of the '413 patent, Merck disclaimed any extension of its term beyond the expiration of the '115 patent and is thus foreclosed from obtaining a term extension under § 156. Hi–Tech asserts that terminal disclaimers are irrevocable and final because the disclaimer is the *sine qua non* for the grant of the patent. Hi–Tech argues that to hold that a terminally disclaimed patent is not barred from obtaining a term extension under § 156 would be contrary to the purpose behind the use of terminal disclaimers because it would effectively uncouple the terminal disclaimer from the original expiration date of the '115 patent. Hi–Tech also argues that such a holding would conflict with this court's prior decisions regarding term extensions and terminal disclaimers in *Merck*, 80 F.3d at 1543, and *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377 (Fed.Cir.2002). Finally, Hi–Tech argues that the PTO regulation that authorizes extension of terminally disclaimed patents, 37 C.F.R. § 1.775, is invalid.

In opposition, Merck argues that § 156 unambiguously states that a patent term "shall be extended" where the conditions enumerated are satisfied. Moreover, it argues that § 156 makes no mention of terminal disclaimers under 35 U.S.C. § 253 and does not prohibit the extension of a patent subject to a § 253 terminal disclaimer. Merck also contends that the term extension provision of § 156 presents no conflict with the terminal disclaimer provision of § 253 and that both sections serve unrelated and independent purposes.

To address the question of whether a patent term extension under 35 U.S.C. § 156 may be applied to a patent subject to a terminal disclaimer, we turn first to the language of § 156. *See Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438, 119 S.Ct. 755, 142 L.Ed.2d 881 (1999) ("As in any case of statutory construction, our analysis begins with 'the language of the statute.' And where the statutory language provides a clear answer, it ends there.") (citations omitted).

[3, 4] While § 156 does not expressly reference terminal disclaimers, it does enumerate other requirements that must be met to obtain a patent term extension.

It states that, if those requirements are met, the patent term "shall be extended." *See* 35 U.S.C. § 156(a). Use of the word "shall" in a statute generally denotes the imperative. *See BlackLight Power, Inc. v. Rogan,* 295 F.3d 1269, 1273 (Fed.Cir.2002) (stating that the word "shall" imposes a duty); *Grav v. United States,* 886 F.2d 1305, 1307–08 (Fed.Cir.1989) (stating that the use of the word "shall" indicates the action is mandatory); *Acuna v. United States,* 202 Ct.Cl. 206, 479 F.2d 1356, 1360 (1973) (same). Nothing in the language of the statute states or suggests that the word "shall" does not mean exactly what it says. Thus, use of the word "shall" indicates that if the enumerated list of requirements is met, the patent term is entitled to be extended. While we find the statutory language unambiguous, we note that the legislative history of the Hatch–Waxman Act, *see* 130 Cong. Rec. 23765 and 24444 (1984), is consistent with our interpretation. *See United States v. Wells,* 519 U.S. 482, 492, 117 S.Ct. 921, 137 L.Ed.2d 107 (1997) (noting that legislative history is consistent with the Court's interpretation of the plain and unambiguous text of the statute); *Whitfield v. United States,* 543 U.S. 209, 210, 125 S.Ct. 687, 160 L.Ed.2d 611 (2005) (same).

Hi–Tech's construction ignores the word "shall" and does not represent the most natural reading of the statutory language. It is not the construction of the statute to which one comes most naturally from the flow of the words and sentences that are used. *See United States v. Nordic Village, Inc.,* 503 U.S. 30, 36, 112 S.Ct. 1011, 117 L.Ed.2d 181 (1992) (stating that it is a "settled rule that a statute must, if possible, be construed in such fashion that every word has some operative effect"); *Demko v. United States,* 216 F.3d 1049, 1053 (Fed.Cir.2000); *LSI Computer Sys., Inc. v. U.S. Int'l Trade Comm'n,* 832 F.2d 588, 590 (Fed.Cir.1987) (stating that "this court will not bend or strain the words of a statute to change its meaning unless there is a persuasive and clear showing that Congress did not intend for the letter of the statute to prevail") (internal quotation omitted).

[5] Moreover, § 156 states that the Hatch–Waxman extension shall run from the expiration date of the patent, as adjusted under section 154(b) to make up for certain PTO delays. In turn, § 154(b)(2)(B) expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays. There is no similar provision that excludes patents in which a terminal disclaimer was filed from the benefits of Hatch–Waxman extensions. The express prohibition against a term adjustment regarding PTO delays, the absence of any such prohibition regarding Hatch–Waxman extensions, and the mandate in § 156 that the patent term *shall* be extended if the requirements enumerated in that section are met, support the conclusion that a patent term extension under § 156 is not foreclosed by a terminal disclaimer. *See Leatherman v. Tarrant County Narcotics Intelligence and Coordination Unit,* 507 U.S. 163, 168, 113 S.Ct. 1160, 122 L.Ed.2d 517 (1993) (observing that an action that is expressly required under one federal rule but not included among the enumerated actions from another federal rule indicates that the action is not a requirement of the later federal rule).

Hi–Tech argues that a construction of the Hatch–Waxman Act that permits patent term extensions for patents subject to terminal disclaimers ignores the fact that the terminal disclaimer was a waiver of patent term and improperly uncouples the '413 terminally disclaimed patent from the '115 patent. We disagree. The expiration date of the patent set by the terminal disclaimer remains in place. The computation of a Hatch–Waxman patent term

extension is from the expiration date resulting from the terminal disclaimer and not from the date the patent would have expired in the absence of the terminal disclaimer. Any waiver of the term is thus not ignored or nullified because the terminal disclaimer provides the date from which the patent term extension begins. The purpose of the terminal disclaimer—to prevent extension of patent term for subject matter that would have been obvious over an earlier filed patent—remains fulfilled by virtue of the fact that the date from which any Hatch–Waxman extension is computed is the terminally disclaimed date. At the same time, the purpose of the patent term extension—to restore some of the patent term lost due to regulatory review—is also satisfied.

The legislative history of § 156 indicates that Congress was aware of concerns over the effects of extending related patents—at least as to parent, continuation, and continuation-in-part patents—and chose to provide the patentee with the option to select to extend the term of only one of either the parent patent or a continuation patent. *See* 130 Cong. Rec. 23765 (1984) ("[O]ne patent on a product, not necessarily the first, can be extended but . . . the total exclusive market life of the product cannot exceed 14 years."); *id.* at 24444 ("The one change involves the rules about which patents can be extended. Under this amendment, the patent holder would be allowed to select the patent to be extended. . . . I believe this amendment is acceptable because it gives the patentholder the flexibility to select the most important patent for extension."). Congress chose not to limit the availability of a patent term extension to a specific parent or continuation patent but instead chose a flexible approach which gave the patentee the choice. We see no reason why a patentee should not have the same choice as between an earlier patent and a later patent related by a terminal disclaimer.

Finally, we disagree with Hi–Tech's argument that to interpret § 156 to permit extension of terminally disclaimed patents conflicts with this court's decisions in Merck and *Bayer*. *Merck* dealt with the interplay between § 156 and the URAA, not the interplay between § 156 and terminal disclaimers under § 253. In Merck, we held that § 156 "requires a more flexible interpretation of the phrase 'original expiration date.'" 80 F.3d at 1551. We stated that "original expiration date" in § 156 "means no more than that the expiration date has not been extended under [§ 156] and, thus, the phrase can identify more than one date." *Id.* In that case, we allowed the patent term as adjusted by the URAA to be extended by the Hatch–Waxman Act. *Bayer* dealt with the interplay between § 253 and the URAA and, like *Merck*, did not deal with the interplay between § 156 and terminal disclaimers under § 253. Although we held in *Bayer* that a terminal disclaimer could not be withdrawn, we did not hold that the terminal disclaimer date cannot be extended by a separate statutory provision. To the contrary, in *Bayer*, this court held that a URAA term extension operates to extend the term of the related terminally disclaimed patent as a matter of law. 298 F.3d at 1381–82. We stated that "[b]ecause the URAA amendments automatically changed the expiration date of the [parent patent] from October 1, 2002 to December 9, 2003, the expiration date of the [terminally disclaimed patent], which is contingent upon the expiration date of the [parent patent], also changed simultaneously to December 9, 2003." *Id.* at 1382–83. Neither of these cases holds or suggests that the express provisions of § 156 are in any way inapplicable to or limited by the presence in a patent of a terminal disclaimer.

[6] For all of the foregoing reasons, we hold that a patent term extension under § 156 may be applied to a patent subject to a terminal disclaimer. We also reject HiTech's assertion of invalidity of 37 C.F.R. § 1.775, the PTO regulation authorizing Hatch–Waxman extensions of terminally disclaimed patents.

CONCLUSION

The judgment of the district court is *AFFIRMED.*

BASF CORPORATION, Plaintiff–Appellant,

v.

UNITED STATES, Defendant–Cross Appellant.

Nos. 05–1477, 05–1523.

United States Court of Appeals, Federal Circuit.

March 29, 2007.

Background: Importer of food colorant challenged Customs Bureau's tariff classification. The United States Court of International Trade, Evan J. Wallach, J., 391 F.Supp.2d 1246, entered judgment for importer. Importer and government appealed.

Holdings: The Court of Appeals, Pauline Newman, Circuit Judge, held that:

(1) eo nomine in the Harmonized Tariff Schedule of the United States (HTSUS) and specificity rules established tariff classification for formulation of beta-carotene as a food colorant, which prevailed over the listing of beta-carotene on the Pharmaceutical Appendix, and

(2) even if food colorant were viewed as a "preparation," the specific tariff classification naming the product would prevail over more general designation.

Judgment appealed; government's appeal denied.

Lourie, Circuit Judge, filed an opinion concurring in part and dissenting in part.

1. Customs Duties ⚿17

The methodology of tariff classification is established by the Harmonized Tariff Schedule of the United States (HTSUS), which consists of the General Notes, the General Rules of Interpretation (GRI), and the Additional United States Rules of Interpretation, including all section and chapter notes and article provisions and the Chemical Appendix; the rules are applied in numerical order.

2. Customs Duties ⚿17

The Harmonized Tariff Schedule of the United States (HTSUS) is a hierarchical classification system which requires application of the most specific descriptive category in determining the applicable duty.

3. Customs Duties ⚿17, 19

When the name of the product and its use are included in an eo nomine description in the Harmonized Tariff Schedule of the United States (HTSUS), that specific classification prevails over a more general classification of either name or use.

4. Customs Duties ⚿17

An eo nomine classification in the Harmonized Tariff Schedule of the United States (HTSUS) describes a product by a specific name.

5. Customs Duties ⚿24(4)

An eo nomine in the Harmonized Tariff Schedule of the United States (HTSUS) and specificity rules established tariff clas-