

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 10,464,992

Inter Partes Review No. IPR2023-00462

**PATENT OWNER'S OBJECTIONS TO EVIDENCE SUBMITTED WITH
THE PETITION FOR *INTER PARTES* REVIEW**

Patent Owner Regeneron Pharmaceuticals, Inc. hereby objects to the following evidence that was submitted by Petitioner Celltrion, Inc. with the Petition (Paper 2) in the above-captioned proceeding.

Exhibit 1002 (Declaration of Dr. Ralph Tarantino (“*Tarantino*”))

Patent Owner objects to Exhibit 1002 under FRE 801-804. The declaration constitutes hearsay to the extent that the declarant has not yet been made available for deposition.

Patent Owner objects to Exhibit 1002 under FRE 402-403. The declaration is irrelevant to the grounds of challenge to the extent it applies incorrect legal standards. The declaration is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, to the extent it relies on the exhibits identified below that were not published before the priority date. Paragraphs 70, 79, and 108 are irrelevant, and their probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, to the extent they rely on information not published before the priority date of the challenged claims of the '992 patent (June 16, 2006). Paragraph 50 is irrelevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder to the extent that it misstates the limitations of the dependent claims, and because it is not cited in the Petition.

Patent Owner objects to Exhibit 1002 under FRE 901. The declaration relies on the unauthenticated evidence identified below. Paragraphs 70, 79, and 108 rely on unauthenticated evidence. It is not clear where the images came from, how they were compiled, or what methods, materials, or metrics were used to arrive at the information in the images.

Patent Owner objects to Exhibit 1002 under FRE 802. The declaration relies on the hearsay evidence identified below. Paragraphs 70 and 79 rely on hearsay offered for the truth of its content without satisfying any of the hearsay exceptions.

Patent Owner objects to Exhibit 1002 under FRE 106 and/or FRE 1006. The declaration relies on excerpts of documents identified below. In fairness, the full document ought to be considered at the same time. Paragraphs 69, 71, 73, 75, 82-87, 153, 156-58, 162-63, and 165 rely on incomplete evidence or improper summary and/or improperly cherry-picking selective passages of a document, while ignoring other passages in the same document.

Patent Owner objects to Exhibit 1002 under FRE 702, 703, and 705. Paragraphs 52-53, 57-58, 60-67, 72, 79-87, 90, 92-102, 105-110, 115, 121-22, 125, 128, 131, 134, 137, 140-143, 147, 149, 150-51, 152-55, 159, 162-63, 165-66, 168, 170-71, 173, 175, 179, 183 of the declaration are not based on sufficient facts or data, are not the product of reliable principles and methods, have not applied the proper principles to the facts of this proceeding.

Exhibit 1006 (Byeong S. Chang & Susan Hershenson, *Practical Approaches to Protein Formulation Development* in RATIONALE DESIGN OF STABLE PROTEIN FORMULATIONS – THEORY AND PRACTICE, 1-25 (J.F. Carpenter and M.C. Manning eds., 2002) (“Chang 2002”))

Patent Owner objects to Exhibit 1006 under FRE 106. Petitioner has filed what appears to be an excerpt of “RATIONALE DESIGN OF STABLE PROTEIN FORMULATIONS – THEORY AND PRACTICE.” The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Patent Owner objects to Exhibit 1006 under FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came from or how it was compiled.

Exhibit 1008 (Napoleone Ferrara & Robert S. Kerbel, *Angiogenesis as a Therapeutic Target*, 438 NATURE 967-74 (Dec. 15, 2005) (“Ferrara 2005”))

Patent Owner objects to Exhibit 1008 under FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

Exhibit 1009 (Hamish M. Fraser et al., *Single Injections of Vascular Endothelial Growth Factor Trap Block Ovulation in the Macaque and Produce a Prolonged, Dose-Related Suppression of Ovarian Function*, 90(2) J. CLIN. ENDOCRINOL. & METAB. 1114-1122 (Feb. 2005) (“Fraser”))

Patent Owner objects to Exhibit 1009 under FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came

from, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the exhibit.

Patent Owner objects to Exhibit 1009 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder to the extent Petitioner fails to show that the exhibit is prior art or fails to show it was publicly accessible before the priority date of the challenged claims of the '992 patent (June 16, 2006). The exhibit does not identify the materials used with specificity and/or Petitioner relies on it to demonstrate properties of materials in other exhibits that are not identified with specificity.

Patent Owner objects to Exhibit 1009 under FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

Exhibit 1010 (Jocelyn Holash et al., *VEGF-Trap: A VEGF Blocker with Potent Antitumor Effects*, 99 (17) PNAS 11393-11398 (Aug. 20, 2002) (“Holash”))

Patent Owner objects to Exhibit 1010 under FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came from, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the exhibit.

Patent Owner objects to Exhibit 1010 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of

confusion of the issues and misleading the fact finder because it does not identify the materials used with specificity and/or because Petitioner relies on it to demonstrate properties of materials in other exhibits that are not identified with specificity.

Patent Owner objects to Exhibit 1010 under FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

Exhibit 1011 (Janeway et al., *The Structure of a Typical Antibody Molecule in IMMUNOBIOLOGY: THE IMMUNE SYSTEM IN HEALTH AND DISEASE*, 5th ed., 94-100 (2001) (“Janeway”))

Patent Owner objects to Exhibit 1011 under FRE 106. Petitioner has filed what appears to be an excerpt of “IMMUNOBIOLOGY: THE IMMUNE SYSTEM IN HEALTH AND DISEASE.” The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Patent Owner objects to Exhibit 1011 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder.

Exhibit 1012 (Leopold K. Kostanski et al., *Size-exclusion Chromatography – a Review of Calibration Methodologies*, 58 J. BIOCHEM. BIOPHYS. METHODS 159-186 (2004) (“Kostanski 2004”))

Patent Owner objects to Exhibit 1012 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder.

Exhibit 1013 (Paul McGoff & David S. Scher., *Solution Formulation of Proteins/Peptides* in PROTEIN FORMULATION AND DELIVERY vol. 99, 139-58 (2000) (“McNally 2000”))

Patent Owner objects to Exhibit 1013 under FRE 106. Petitioner has filed what appears to be an excerpt of “PROTEIN FORMULATION AND DELIVERY.” The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Patent Owner objects to Exhibit 1013 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder.

Exhibit 1015 (J.S. Rudge et al., *VEGF Trap as a Novel Antiangiogenic Treatment Currently in Clinical Trials for Cancer and Eye Diseases*, and *VelociGene®-based Discovery of the Next Generation of Angiogenesis Targets*, 70 COLD SPRING HARBOR SYMPOSIA ON QUANTITATIVE BIOLOGY 411-418 (2005) (“Rudge”))

Patent Owner objects to Exhibit 1015 under FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came from or how it was compiled.

Patent Owner objects to Exhibit 1015 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder to the extent Petitioner fails to show that the exhibit is prior art or fails to show it was publicly accessible before the priority date of the challenged claims of the '992 patent (June 16, 2006). The exhibit does not identify the materials used with specificity and/or Petitioner relies on it to demonstrate properties of materials in other exhibits that are not identified with specificity.

Patent Owner objects to Exhibit 1015 under FRE 802. The exhibit it is offered for the truth of its content without satisfying any of the hearsay exceptions.

Exhibit 1016 (Christine Wulff et al., *Prevention of Thecal Angiogenesis, Antral Follicular Growth, and Ovulation in the Primate by Treatment with Vascular Endothelial Growth Factor Trap R1R2*, 143(7) ENDOCRINOLOGY 2797-2807 (Jul. 2002) (“Wulff”))

Patent Owner objects to Exhibit 1016 under FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear where the exhibit came from, how it was compiled, or what methods, materials, or metrics were used to arrive at the information in the exhibit.

Patent Owner objects to Exhibit 1016 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it does not identify the materials used with specificity and/or because Petitioner relies on it to demonstrate properties of materials in other exhibits that are not identified with specificity.

Patent Owner objects to Exhibit 1016 under FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

Exhibit 1018 (U.S. Patent No. 6,171,586 to Lam et al. (“’586 Patent”))

Patent Owner objects to Exhibit 1018 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder. The exhibit is not specific

about the methods and materials used. The exhibit is not reasonably related to the claim language.

Exhibit 1019 (U.S. Patent No. 7,374,758 to Papadopoulos et al. (“’758 Patent”))

Patent Owner objects to Exhibit 1019 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder. It does not identify the materials used with specificity and/or because Petitioner relies on it to demonstrate properties of materials in other exhibits that are not identified with specificity. It was not published before the priority date of the challenged claims of the ’992 patent (June 16, 2006).

Patent Owner objects to Exhibit 1019 under FRE 802. The exhibit because it is offered for the truth of its content without satisfying any of the hearsay exceptions.

Exhibit 1020 (Application for Extension of Patent Term to U.S. Patent No. 7,374,758 (“’758 PTE”))

Patent Owner objects to Exhibit 1020 under FRE 106. Petitioner has filed what appears to be an excerpt of the ’758 patent’s file history. The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Patent Owner objects to Exhibit 1020 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it was not published before the priority date of the challenged claims of the '992 patent (June 16, 2006).

Exhibit 1021 (U.S. Patent No. 8,110,546 to Dix et al. (“Dix”))

Patent Owner objects to Exhibit 1021 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder. It does not identify the materials used with specificity and/or because Petitioner relies on it to demonstrate properties of materials in other exhibits that are not identified with specificity. It was not published before the priority date of the challenged claims of the '992 patent (June 16, 2006).

Patent Owner objects to Exhibit 1021 under FRE 802. The exhibit because it is offered for the truth of its content without satisfying any of the hearsay exceptions.

Exhibit 1022 (Declaration Pursuant to 37 C.F.R. § 1.131 of Daniel B. Dix, Kelly Frye, and Susan Kautz in Support of U.S. Application No. 12/835,065 (“Declaration of Dix et al.”))

Patent Owner objects to Exhibit 1022 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder. The exhibit was not

published before the priority date of the challenged claims of the '992 patent (June 16, 2006). The exhibit does not identify the materials and methods used with specificity and/or Petitioner relies on it to demonstrate properties of materials in other exhibits that are not identified with specificity.

Exhibit 1023 (Response to Office Action of July 13, 2011 in U.S. Application No. 12/835,065 (“Nov 22 OA Response”))

Patent Owner objects to Exhibit 1023 under FRE 106. Petitioner has filed what appears to be an excerpt of the file history for Application No. 12/835,065. The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Patent Owner objects to Exhibit 1023 under FRE 402 and 403. It is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it was not published before the priority date of the challenged claims of the '992 patent (June 16, 2006).

Exhibit 1024 (U.S. Patent Publication No. 2003/0113316 to Kaisheva et al. (“Kaisheva '316”))

Patent Owner objects to Exhibit 1024 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder. The exhibit is not specific

about the methods and materials used. The exhibit is not reasonably related to the claim language.

Exhibit 1025 (U.S. Patent Publication No. 2003/0138417 to Kaisheva et al. (“*Kaisheva* ’417”))

Patent Owner objects to Exhibit 1025 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder. The exhibit is not specific about the methods and materials used. The exhibits are not reasonably related to the claim language.

Exhibit 1026 (U.S. Patent Publication No. 2004/0197324 to Liu et al. (“*Liu*”))

Patent Owner objects to Exhibit 1026 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder. The exhibit is not specific about the methods and materials used. The exhibit is not reasonably related to the claim language.

Exhibit 1027 (U.S. Patent Publication No. 2004/0265309 to Kandel et al. (“’309 *Publication*”))

Patent Owner objects to Exhibit 1027 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it does not identify

the materials used with specificity and/or because Petitioner relies on it to demonstrate properties of materials in other exhibits that are not identified with specificity.

Exhibit 1028 (U.S. Patent Publication No. 2005/0112061 to Holash et al. (“’061 Publication”))

Patent Owner objects to Exhibit 1028 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it does not identify the materials used with specificity and/or because Petitioner relies on it to demonstrate properties of materials in other exhibits that are not identified with specificity.

Exhibit 1029 (International Publication No. WO 00/75319 to Papadopoulos et al. (“’319 Publication”))

Patent Owner objects to Exhibit 1029 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it does not identify the materials used with specificity and/or because Petitioner relies on it to demonstrate properties of materials in other exhibits that are not identified with specificity.

Exhibit 1030 (International Publication No. WO 97/04801 to Andya et al. (“WO ’801”))

Patent Owner objects to Exhibit 1030 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder. The exhibit is not specific about the methods and materials used. The exhibit is not reasonably related to the claim language.

Exhibit 1031 (*Vial*, Merriam-Webster.com, <https://merriam-webster.com/dictionary/vial> (last visited Jan. 16, 2023) (“*Merriam Webster Vial Definition*”))

Patent Owner objects to Exhibit 1031 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it was not published before the priority date of the challenged claims of the ’992 patent (June 16, 2006).

Exhibit 1032 (AVASTIN[®], *Approved Labeling*, Center for Drug Evaluation and Research (2004) (“*AVASTIN Label*”))

Patent Owner objects to Exhibit 1032 under FRE 901. Petitioner has not demonstrated the authenticity of the exhibit. It is not clear that this exhibit is an accurate representation of any labeling that was publicly accessible before the priority date of the challenged claims of the ’992 patent (June 16, 2006).

Patent Owner objects to Exhibit 1032 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder to the extent Petitioner fails to show it was publicly accessible before the priority date of the challenged claims of the '992 patent (June 16, 2006).

Patent Owner objects to Exhibit 1032 under FRE 802. The exhibit is offered for the truth of its content without satisfying any of the hearsay exceptions.

Exhibit 1033 (RAPTIVA[®], *Physicians' Desk Reference* (59th ed. 2005) (“RAPTIVA Label”))

Patent Owner objects to Exhibit 1033 under FRE 106. Petitioner has filed what appears to be an excerpt of “Physician’s Desk Reference.” The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1034 (REMICADE[®], *Physicians' Desk Reference* (59th ed. 2005) (“REMICADE Label”))

Patent Owner objects to Exhibit 1034 under FRE 106. Petitioner has filed what appears to be an excerpt of “Physician’s Desk Reference.” The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1035 (SIMULECT[®], *Physicians' Desk Reference* (59th ed. 2005) (“*SIMULECT Label*”))

Patent Owner objects to Exhibit 1035 under FRE 106. Petitioner has filed what appears to be an excerpt of “Physician’s Desk Reference.” The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1036 (HERCEPTIN[®], *Physicians' Desk Reference* (59th ed. 2005) (“*HERCEPTIN Label*”))

Patent Owner objects to Exhibit 1036 under FRE 106. Petitioner has filed what appears to be an excerpt of “Physician’s Desk Reference.” The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1037 (XOLAIR[®] label, *Physicians' Desk Reference* (59th ed. 2005) (“*XOLAIR Label*”))

Patent Owner objects to Exhibit 1037 under FRE 106. Petitioner has filed what appears to be an excerpt of “Physician’s Desk Reference.” The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1039 (Excerpts from Prosecution History of U.S. Application No. 11/818,463 (“’463 Excerpts”))

Patent Owner objects to Exhibit 1039 under FRE 106. Petitioner has filed what appears to be an excerpt of the ’463 application’s prosecution history. The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1040 (Excerpts from Prosecution History of U.S. Application No. 12/560,885 (“’885 Excerpts”))

Patent Owner objects to Exhibit 1040 under FRE 106. Petitioner has filed what appears to be an excerpt of the ’885 application’s prosecution history. The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1041 (Excerpts from Prosecution History of U.S. Application No. 12/833,417 (“’417 Excerpts”))

Patent Owner objects to Exhibit 1041 under FRE 106. Petitioner has filed what appears to be an excerpt of the ’417 application’s prosecution history. The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1042 (Excerpts from Prosecution History of U.S. Application No. 13/329,770 (“’770 Excerpts”))

Patent Owner objects to Exhibit 1042 under FRE 106. Petitioner has filed what appears to be an excerpt of the ’770 application’s prosecution history. The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Patent Owner objects to Exhibit 1042 under FRE 402 and 403. The exhibit is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it was not discussed in the Petition or in Petitioner’s expert declaration.

Exhibit 1043 (Excerpts from Prosecution History of U.S. Application No. 13/914,996 (“’996 Excerpts”))

Patent Owner objects to Exhibit 1043 under FRE 106. Petitioner has filed what appears to be an excerpt of the ’996 application’s prosecution history. The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1044 (Excerpts from Prosecution History of U.S. Application No. 14/330,096 (“’096 Excerpts”))

Patent Owner objects to Exhibit 1044 under FRE 106. Petitioner has filed what appears to be an excerpt of the ’096 application’s prosecution history. The

remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1045 (Excerpts from Prosecution History of U.S. Application No. 15/095,606 (“’606 Excerpts”))

Patent Owner objects to Exhibit 1045 under FRE 106. Petitioner has filed what appears to be an excerpt of the ’606 application’s prosecution history. The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1046 (Excerpts from Prosecution History of U.S. Application No. 15/879,294 (“’294 Excerpts”))

Patent Owner objects to Exhibit 1046 under FRE 106. Petitioner has filed what appears to be an excerpt of the ’294 application’s prosecution history. The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

To the extent the exhibits are admitted, their scope should be restricted to the purpose for which they were originally submitted. FRE 105. Should Petitioner rely on an exhibit for a different purpose than the one for which it has been offered, Patent Owner reserves the right to make additional objections.

In accordance with 37 C.F.R. § 42.64(b)(1), these objections are being timely filed and served within ten (10) business days of the institution of the trial by the Patent and Trial Appeal Board (“Board”), which is reflected in the Board’s Institution Decision dated July 20, 2023 (Paper 11).

Dated: August 3, 2023

Respectfully submitted,

By /Adam R. Brausa/
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Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached PATENT OWNER'S OBJECTIONS TO EVIDENCE SUBMITTED WITH THE PETITION FOR *INTER PARTES* REVIEW was served as of the below date on the Petitioner via e-mail (by agreement) to the following counsel of record.

Lora M. Green (USPTO Reg. No. 43,541)
Robert Cerwinski (*pro hac vice*, pending)
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Dated: August 3, 2023

/Adam R. Brausa/
Adam R. Brausa, Reg. No. 60,287