

O Sun God, Savitr!
Thou dazzling fount of life-persuasive light!
Sublimest mystery speeding from afar!
Swift became that burst too potent on the sight!
This radiant type of strength and youth!
Glowing eternally!



శ్రీ వేపచేదు విద్యా పీఠము

May the golden-eyed Savitar come hither!
Steering forth he rises from the lap of the dawn!
Praised by singers, my God Savitar!
Stopped forth and never missed his place!
He steps forth the splendor of the sky the wide!
Seeing, far-shining, the shining wanderer!
- Rig Veda. vii. 65

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We alone shine!
All luminaries get illuminated by His Illumination!
The whole Universe is enlightened by His light!
- Kathopanishad

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Dr. Sreenivasarao Vepachedu¹, JD, PhD, LLM

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INEQUITABLE CONDUCT CONTINUES TO HAUNT AMERICAN PATENTS

Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent². Unlike validity defenses, which are claim specific, inequitable conduct regarding a single claim renders the entire patent unenforceable.³

But for Material

As a general matter, the materiality required to establish inequitable conduct is but-for materiality⁴. A prior art reference is “but-for material” if the PTO would not have allowed a claim had it been aware of the undisclosed prior art⁵. In determining the materiality of a reference, the court applies the preponderance of the evidence standard and gives claims their broadest reasonable construction⁶. A reference is not but-for material, however, if it is merely cumulative⁷. A reference is cumulative when it “teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO⁸.”

Materiality of Withheld References

In addition to proving the materiality of withheld references, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO⁹. A court must weigh the evidence of intent to deceive independent of its analysis of materiality. Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive¹⁰.” In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference¹¹.

Inference of Intent to Deceive

Direct evidence of intent is not, however, required. A court may infer intent from circumstantial evidence¹². An inference of intent to deceive is appropriate where the applicant engages in “a pattern of lack of candor,” including where the applicant repeatedly makes factual representations “contrary to the true information he had in his possession¹³.”

Claim Construction

When primary focus is on inequitable conduct, the Court applies the broadest reasonable construction to determine claim scope. The transitional term ‘comprising,’ which is synonymous with ‘including,’

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Skimming forth he rises from the lap of the dawn!
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‘containing,’ or ‘characterized by,’ is inclusive or open-ended and does not exclude additional, un-recited elements or method steps¹⁴. Because “comprise” is inclusive or open ended, the use of the term does not exclude un-recited elements¹⁵. A germline that “comprises” human variable region gene segments may very well also include human constant gene segments. Thus, the “customary and ordinary” meaning of the language in claim 1 is not limited to a reverse chimeric mouse¹⁶.

Invalidation of Patent Due to Inequitable Conduct of Regeneron

The first step in an inequitable conduct inquiry is determining whether the patentee failed to disclose but-for material information to the PTO. Determining but-for materiality requires that the court place itself in the shoes of a patent examiner and determine whether, had the reference(s) been before the examiner at the time, the claims of the patent would have still issued¹⁷.

Both Regeneron and Merus agree that the claimed mouse has, as recited in claim 1, “human un-rearranged variable region gene segments.” Further, as explained above, the “customary and ordinary” meaning of the language in claim 1 is not limited to a reverse chimeric mouse.

In a January 2013 Reply to the Final Office Action, Regeneron amended claim 1 to include the additional limitation that the human un-rearranged variable region gene segments would be inserted at “an endogenous” mouse immunoglobulin locus. Regeneron also sent a presentation to the PTO with the Reply. In that presentation, Regeneron asserted that it had developed a commercial embodiment of the claimed mouse with surprising results. It is undisputed that that assertion was false. Regeneron had not developed any such mouse at the time. The USPTO maintained the rejection in an advisory action. Drs. Jones and Smeland together a misleading presentation asserting that Regeneron had developed a commercial embodiment of the claimed mouse. Following that meeting, the PTO issued a Notice of Allowance for the ’176 application, stating that the prior art does not teach or suggest a genetically modified mouse comprising, in its germline cells, human un-rearranged variable region gene segments inserted at an endogenous mouse immunoglobulin locus.” However, the Withheld References were “**but for material**” for the allowed claim.

According to CAFC, the district court stated explicitly that it was troubled by Regeneron’s refusal at a hearing. At that time, experienced patent counsel asserted that he did not understand what the district court was asking for or how to break a claim down into elements. The district court determined that this

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obfuscation made no sense and was a tactical choice—seeking to shift the plaintiff’s burden in an infringement case to define the elements of a claim to the defendant. During claim construction, Regeneron again chose tactics over substance. The district court issued an order expressing its concern that Regeneron was attempting to “game” the system by shifting the burden to Merus to propose constructions and then to take shots at those proposals¹⁸. The district court explained that Regeneron’s behavior with respect to the Jones Memo was relevant for first, Regeneron’s behavior followed the pattern of misconduct described above, and second, Regeneron sought to use the memo as a cloak for its later misconduct.

The CAFC found that evidence supported the district court’s finding of but-for materiality of the withheld references and affirmed¹⁹ the District Court’s holding of unenforceability of ’018 patent due to Regeneron’s inequitable conduct²⁰.

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UPDATE ON PATENTS

RUSSIAN FEDERATION:



The Hague Agreement is designed to facilitate the protection of industrial designs in multiple countries or regions by allowing applicants to file a single application in a single language (English, French or Spanish). The Hague Agreement was first adopted in 1925, as amended by the Geneva Act of July 2, 1999²¹. More than 50 states and inter-governmental organizations are members of the Geneva Act of the Hague Agreement, including the European Union, the African Intellectual Property Organisation, the United States, Japan, South Korea and the United Kingdom. The Russian Federation signed the Geneva Act on July 6, 1999 but did not ratify it until March 29, 2017, when the Russian Federation Council approved the Law on Ratification of the Geneva Act of the Hague Agreement. The law was signed by the Russian President on April 3 and will be effective October 1, 2017²².

Russia requires substantive examination, and may refuse protection for industrial designs within 12 months from the date of publication of the international registration. The period of industrial design protection is 25 year, with the possibility of renewing every five-year.

INDIAN UNION:



From 3rd July 2017 the patent certificates will be generated through an automated system after the patent is granted by the Controller and shall be made available on the official website and transmitted to the applicants concerned or their authorized patent agents at the email address on record. Applicants are advised to update on the e-filing portal with a valid email address.

Indian Patent Office is now available as a Receiving Office²³ and an International Searching Authority (ISA)²⁴.

Fee

Search fee (Rule 16.1(a))
Additional fee (Rule 40.2(a))
Protest fee (Rule 40.2(e) and 68.3(e))
Late furnishing fee (Rule 13ter.1(c) and 13ter.2)

Indian Rupees (INR)

10,000 (2,500 for an individual)
10,000 (2,500 for an individual)
4,000 (1,000 for an individual)
4,000 (1,000 for an individual)



The Indian Receiving Office requires an address for service in India, but there is no need for an agent. Electronic filing is available²⁵.

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However, it should be noted that unless there is a bilateral agreement between the IPO and the USPTO regarding the IPO-ISA/IPEA, American inventors and applicants cannot avail the opportunity to use the IPO-ISA.

On 29 June 2017, the Ministry of Consumer Affairs, Food and Public Distribution of India has approved amendments to the Legal Metrology Packaged Commodities Rules, 2011 (PCR Amendments), effective from 1 January 2018. Medical devices such as stents, valves, orthopedic implants, syringes, tools for operations, etc., are declared as drugs under the Drugs and Cosmetics Act, 1940. The PCR Amendments mandatorily require drugs to display Maximum Retail Price (MRP) along with other declarations as required under the PCR.

IPO on Computer Related Inventions (CRIs): The IPO has issued revised guidelines for examination of CRIs on 30 June 2017 (Revised Guidelines), effective immediately. The Revised Guidelines do not expressly lay down any specific tests, indicators, or determinants on patentability of CRIs, but removed illustrative examples on non-patentable and patentable claims.

Reminder: The Indian patent applications shall be examined only on filing the request for substantive examination within 48 months from the priority date of the application or from the date of filing the application whichever is earlier. If the request is not filed the application shall be deemed to have been withdrawn by the applicant. Within 1 month from the date of the application publication or 1 month from the date of the request for examination whichever is later, the Controller refers the application and specification and other documents to the Examiner, who submits a report to the Controller ordinarily within one month but not exceeding 3 months from the date of reference of the application by the Controller, who would dispose of the report within one month from the date of receipt of such report and issue the first examination report - ordinarily within 6 months from the date of the request for the examination or from the date of publication whichever is later.

Technology and Innovation Support Center²⁶: The WIPO Technology and Innovation Support Center (TISC) program provides innovators in developing countries with access to locally based, high quality technology information and related services, helping them to exploit their innovative potential and to create, protect, and manage their intellectual property (IP) rights. Over 500 TISCs operate worldwide. Services offered by TISCs may include:

- Access to online patent and non-patent (scientific and technical) resources and IP-related publications;
- Assistance in searching and retrieving technology information;

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- Training in database search;
- On-demand searches (novelty, state-of-the-art and infringement);
- Monitoring technology and competitors;
- Basic information on industrial property laws, management and strategy, and technology commercialization and marketing.

The Department of Industrial Policy and Promotion (DIPP) of India and World Intellectual Property Organization (WIPO) have signed an agreement to establish Technology and Innovation Support Centers (TISC) and the Cell for IPR Promotion and Management (CIPAM) is designated as the National Focal point for the TISC national network.

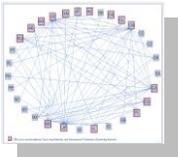
CYPRUS²⁷: Amendments to the IP Box Regime in order to comply with the guidelines and requirements of the OECD. The new amendments bring the legislation in Cyprus on the taxation of Royalties (IP Box) in full compliance with OECD. Although the old IP box regime will continue to apply to Qualifying IP, until the end of June 2021, the amendments are effective as from 30th of June 2016. A Qualifying IP that was acquired directly or indirectly from a related person during the period from 2nd of January 2016 until 30th of June 2016.



PHILIPPINES²⁸: The Patent Prosecution Highway (PPH) Pilot Program between the Intellectual Property Office of the Philippines (IPOP) and the European Patent Office (EPO) took effect on 01 July 2017. PPH leverages on the fast-track patent examination procedures already available in the IP Offices to allow applicants to obtain corresponding patents faster and more efficiently. The IPOP-EPO PPH Pilot Program replicates the participation conditions and requirements currently applied in PPH Programs operational worldwide, in particular the IP5 and the Global PPH (GPPH) Programs. It also reflects the PPH Global Principles developed within the framework of the PPH Working Group.



PATENT PROSECUTION HIGHWAY (PPH)²⁹: A unified PPH Form has been adopted by 19 countries and regions including China, Europe, Sweden, Finland, Austria, Israel, Hungary, Spain, Portugal, Norway, Australia, the United States, Russia, Canada, Denmark, the United Kingdom, South Korea, Japan, and Egypt.



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UPDATE ON TRADEMARKS

INDIA: Opposition Due Within 4 Months From The Publication Date



Trade Marks Act § 42³⁰. Notice of Opposition. - (1) A notice of opposition to the registration of a trademark under sub-section (1) of section 21, with such particulars as specified in Rule 43, shall be filed in Form TM-0 within four months from the date of publication of the trademark journal in which the application for registration of the trademark was advertised or re advertised.

Counterstatement: Due Date Is 2 Months From The Notice Of Opposition

Trade Marks Act § 44 (1) The counterstatement required by sub-section (2) of section 21 shall be sent on Form TM-0 within two months from the receipt by the applicant of the copy of the notice of opposition from the Registrar and shall set out what facts, if any, alleged in the notice of opposition, are admitted by the applicant. A copy of the counterstatement shall be ordinarily served by the Registrar to the opponent within two months from the date of receipt of the same.

CAYMAN ISLANDS (KY)³¹: The Patent, Trademarks, and Design Rights Registration Laws adopted on



December 19, 2016, **effective from August 1, 2017**, were published on May 26, 2017, liberating the Cayman Islands' Trademark law from the UK/EU dependence. Under the new Trademarks Law, Cayman Islands' TMs can be obtained directly from Cayman Islands. It is no longer necessary to register TMs in UK/EU to obtain Cayman Islands' TMs.

Disclaimer³²: Every effort has been made to verify the accuracy of items in the Quarterly IP Law Update. However, readers are urged to check independently on specific matters from their corresponding foreign agents. For further information or support, please contact the editor³³.

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REFERENCES AND NOTES³⁴

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² Therasense, 649 F.3d at 1285.

³ Id. at 1288. Inequitable conduct has two separate requirements: materiality and intent. Id. at 1290.

⁴ Id. At 1291

⁵ Id

⁶ Id. at 1291–92.

⁷ See Dig. Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1319 (Fed. Cir. 2006)

⁸ Regents of the Univ. of Calif. v. Eli Lilly & Co., 119 F.3d, 1559, 1575 (Fed. Cir. 1997)

⁹ Therasense, 649 F.3d at 1290.

¹⁰ Id

¹¹ Id. (quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995)) (internal quotation marks omitted).

¹² Id

¹³ Id

Apotex Inc. v. UCB, Inc., 763 F.3d 1354, 1362(Fed. Cir. 2014).

¹⁴ MPEP § 2111.03

¹⁵ Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997)

¹⁶ REGENERON PHARMACEUTICALS, INC., v MERUS N.V. 2016-1346, July 27, 2017:

<http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/16-1346.Opinion.7-24-2017.1.PDF>

¹⁷ Therasense, 649 F.3d at 1291–92.

¹⁸ Discovery Order #5, Regeneron Pharm., Inc. v. Merus B.V., No. 14-cv-1650, 2014 WL 3865366, at *1

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O Sun God, Savitr!
Thou dazzling fount of life-persuasive light!
Sublimest mystery speeding from afar!
Swift became that burst too potent on the sight!
This radiant type of strength and youth!
Glowing eternally!



శ్రీ వేపచేదు విద్యా పీఠము

May the golden-eyed Savitar come hither!
Steering forth he rises from the lap of the dawn!
Praised by singers, my God Savitar!
Stopped forth and never missed his place!
He steps forth the splendor of the sky the wide!
Seeing, far-shining, the shining wanderer!
-Rig Veda. vii. 65

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He alone shines!
All luminaries get illuminated by His Illumination!
The whole Universe is enlightened by His light!
-Kathopanishad

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(S.D.N.Y. July 22, 2014), Dkt. No. 81.

¹⁹ Regeneron Pharmaceuticals, Inc. v. Merus N.V. (Federal Circuit 2017)

<http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/16-1346.Opinion.7-24-2017.1.PDF>

²⁰ Regeneron Pharmaceuticals v. Merus B.V., 144 F. Supp. 3d 530 (S.D.N.Y. 2015) ("Dist. Ct. Op.")

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²² The Accession of the Russian Federation to the Geneva Act of the Hague Agreement

http://www.wipo.int/edocs/mdocs/hague/en/h_sym_ge_14/h_sym_ge_14_ref_kiriy.pdf; Russia Ratifies Geneva Act Of Hague Agreement On Industrial Designs: <https://www.petosevic.com/resources/news/2017/04/3690>; Updates on documents signed <http://en.kremlin.ru/acts/news/54183>;

²³ Receiving Offices, INDIAN PATENT OFFICE: http://www.wipo.int/pct/guide/en/gdvol1/annexes/annexc/ax_c_in.pdf

²⁴ International Searching Authorities, INDIAN PATENT OFFICE

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²⁵ Receiving Offices, INDIAN PATENT OFFICE: http://www.wipo.int/pct/guide/en/gdvol1/annexes/annexc/ax_c_in.pdf

²⁶ Technology and Innovation Support Center <http://pib.nic.in/newsite/PrintRelease.aspx?relid=161624>

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²⁸ IMPLEMENTATION OF THE PATENTPROSECUTION HIGHWAY (PPH) PILOTPROGRAMME BETWEEN THE INTELLECTUALPROPERTY OFFICE OF THE PHILIPPINES ANDTHE EUROPEAN PATENT OFFICE:

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²⁹ Unified PPH Request Form Adopted by 19 PPH Authorities:

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³⁰ GOVERNMENT OF INDIA MINISTRY OF COMMERCE AND INDUSTRY (DEPARTMENT OF INDUSTRIAL POLICY AND PROMOTION) Notification 6 March 2017: The Trade Marks Rules

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India Announces New Trade Mark Rules

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³¹ CAYMAN ISLANDS GAZETTE: <http://www.gov.ky/portal/pls/portal/docs/1/12418495.PDF>

³² **Disclaimer:** Although every effort has been made to provide accurate information from reputable sources, the content of this law update is a general guide and CIP or the author is not responsible for inadvertent errors and/or

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any inaccuracies of the matter obtained from various resources cited therein. Specialist or registered agent's advice should be sought about your specific circumstances and specific country.

³³ Dr. Rao Vepachedu at rao.vepachedu@cardinal-ip.com.

³⁴ In addition to the primary sources cited above, additional references include:

New York Times, Washington Post, Mercury News, Bayarea.com, Deccan Chronicle, the Hindu, Hindustan Times, Times of India, AP, Reuters, AFP, The Guardian, Pravda, Spiegel, Connexion, etc.

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"Where the mind is without fear and the head is held high, Where knowledge is free Where the world has not been broken up into fragments, By narrow domestic walls." Rabindranath Tagore (1861-1941), Gitanjali, 1912.

One World One Family

AUM! SWASTI!

Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih! (Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

SWASTI! AUM!

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