Evolution of organisms and their nomenclature in microbiology patents
Taxonomic and phylogenetic considerations for innovators

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Abstract Organisms are complex biological entities that are less easily defined by specific structures than molecules, nucleic acids, and antibodies. Yet these small molecules and biopolymers were the focus of many cases shaping modern patent law, which emphasizes the importance of defining biological inventions in terms of structure. Nor are organisms necessarily fixed in time or reproducible by repeatable methods—as molecules, nucleic acids, and antibodies may be—given their capacity for replication and mutation. And like organisms themselves, names and classifications also change over time as understanding of extant biodiversity advances. But this capacity for change over a 20-year patent term stands in tension with the law's focus on the state of the art at the time a patent application is filed.

Here, I review the challenges evolution poses for patentees, such as the changing nature of bacterial classifications and short-term evolution that may occur over a patent term, and Federal Circuit decisions relevant to each issue. This work concludes that careful consideration of organisms' evolutionary histories and the taxonomy and phylogenetics underlying their classification in application drafting may be useful in: (i) mitigating the impact of scientific disagreement (such as the 'species problem' in microbiology) in claim interpretation; (ii) limiting the effects of changing classifications on infringement determinations; (iii) describing the diversity within taxa in sufficient detail to encompass later-arising organisms; and (iv) linking the biology underlying an invention to the depth of conservation to bolster compliance with the written description and enablement requirements of 35 U.S.C. § 112(a). Accordingly, patentees might address the challenges that evolutionary uncertainty poses for organism-centered patents by embracing these areas of evolutionary biology.

Jacobs NT. Clades, classifications, and claims: evolution of organisms and their nomenclature in life science patents. *J Law Biosci*. 2025;12(2):lsaf026 (PMID 41179233)

wolf greenfield

Context: Patents are Written Representations of Tangible Entities

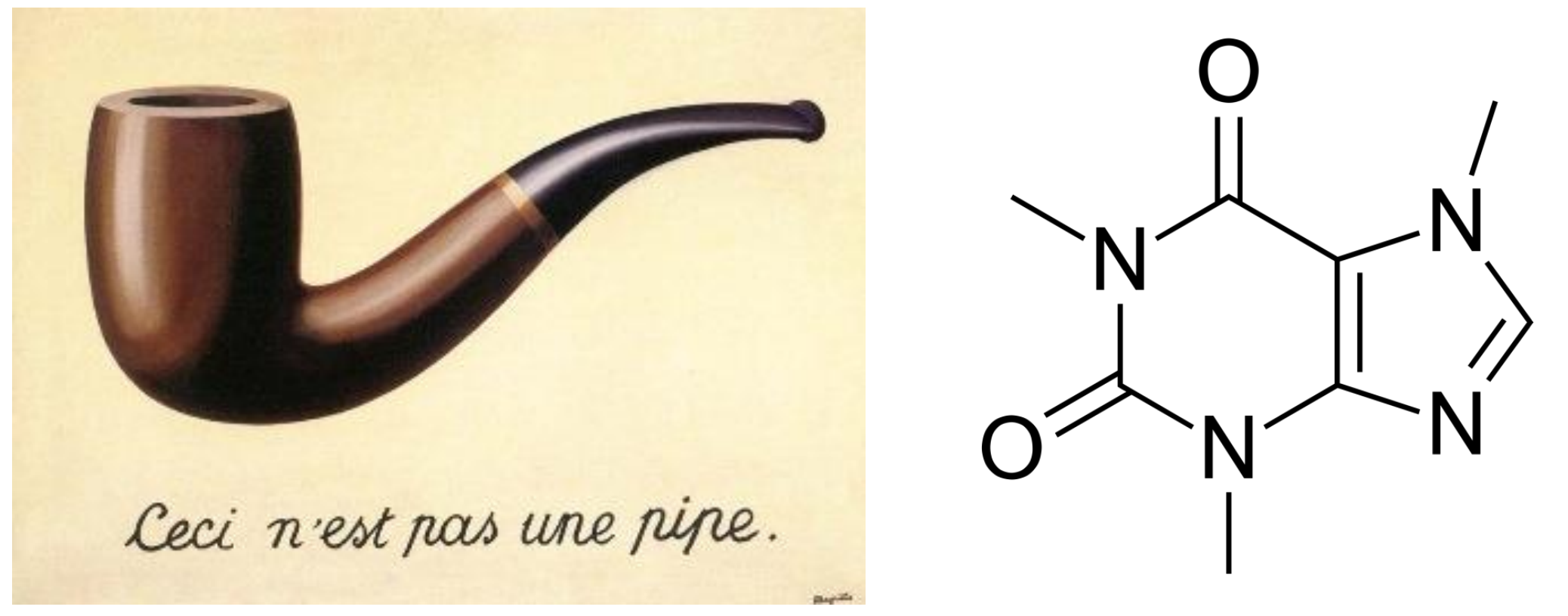


Fig. 1. Patents are written documents, with claims defining the invention, but the *things* patented are the physical objects themselves, not their representations. *In re Papesch*. (Left) *The Treachery of Images* ("This is not a pipe"), Magritte. **(Right)** Chemical structure of caffeine, whose relatives were claimed in *Papesch*.

Definitional Options	Questions
A bacterium having deposit number ATCC 15692 or descendant thereof.	• What **diversity** is encompassed by this classification? • Is this level of specificity **necessary** to distinguish from the prior art? • What **structural features** are shared by bacteria circumscribed? • What are the **functional characteristics** implied by structural commonalities? • How do l**ater reclassifications** or knowledge affect interpretation or compliance with description, enablement, and clarity requirements?
A bacterium belonging to the GTDB species cluster *Pseudomonas aeruginosa*.	
A bacterium comprising a genome with at least [95.0%, ~97%, 99.5%, 99.99%] ANI to the genome of GCF_001729505.1.	
A bacterium comprising a 16S rRNA gene sequence with at least [97.0%, 98.7%, 99.0%] identity to Accession No. PP064586.1.	

Table 1. Bacteria may be recited in claims in terms of a physical deposit, taxonomic name, or sequence-based identity measure. Each has implications for scope, clarity, and sufficient description and enablement.

The evolutionary history and relatedness of organisms are central to the working of many inventions in biotechnology, such as live biotherapeutic products, direct-fed microbials, and postbiotics. Where utility is shown in one organism, the question arises of which related organisms may share similar utility. **Table 1**.

Complicating the issue is the difficulty in defining organisms, as physical, replicating entities in claim language, in contrast to small molecules or proteins such as antibodies that are more easily defined by a chemical structure or amino acid sequence. **Fig. 1**. Depositing an organism is one manner of definition, but may limit claim scope more than necessary to distinguish from the prior art. *Genzyme*, *Intervet*. On the other hand, claims encompassing whole categories of organisms, such as those defining an organism by a certain similarity to a reference sequence or membership in a named taxon, pose their own challenges. In small molecule and antibody cases, Federal Circuit has recently treated these "genus" claims increasingly negatively, invalidating multiple patents, with respect to the written description and enablement requirements. Karshtedt.

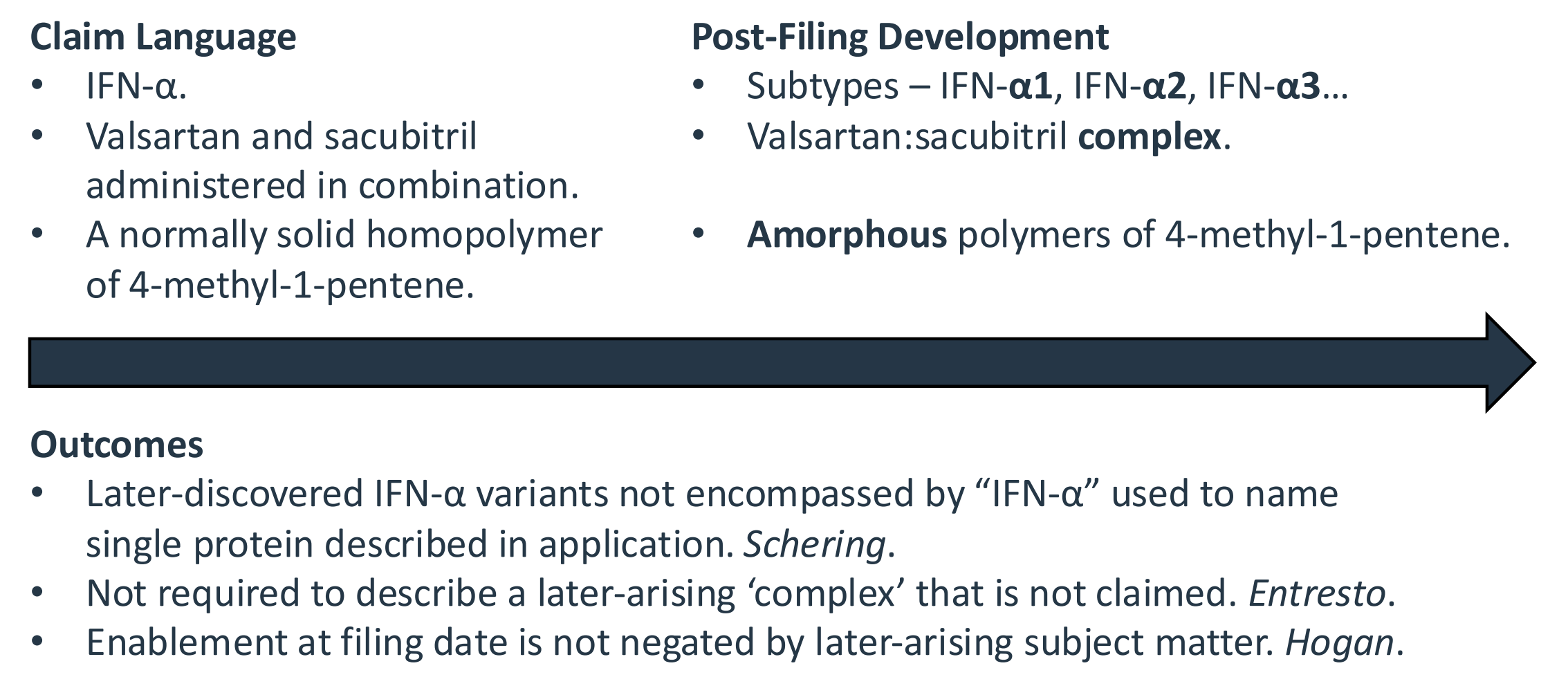
Systematics, including taxonomy and phylogenetics, addresses similar issues with respect to circumscribing groups of organisms based on their genetic similarity and evolutionary relationships. Accordingly, applicants for organism-centered patents may describe genomes of relevant organisms, classification frameworks, and diversity within taxa to support genus claims encompassing related organisms.

Relevant Cases & Article

In re Papesch, 135 F.2d 381 (C.C.P.A. 1963)
Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094 (Fed. Cir. 2003)
Intervet Inc. v. Merial Ltd, 617 F.3d 1282 (Fed. Cir. 2010)

Karshtedt *et al.*, The Death of the Genus Claim, 35 Harv. J. L. & Tech. 1 (Fall 2021)

Problem: Evolution in Tension with Patent Description, Enablement, Clarity Requirements



Claim Language
- IFN-α.
- Valsartan and sacubitril administered in combination.
- A normally solid homopolymer of 4-methyl-1-pentene.

Post-Filing Development
- Subtypes – IFN-**α1**, IFN-**α2**, IFN-**α3**…
- Valsartan:sacubitril **complex**.
- **Amorphous** polymers of 4-methyl-1-pentene.

Outcomes
- Later-discovered IFN-α variants not encompassed by "IFN-α" used to name single protein described in application. *Schering*.
- Not required to describe a later-arising 'complex' that is not claimed. *Entresto*.
- Enablement at filing date is not negated by later-arising subject matter. *Hogan*.

Fig. 2. Claim interpretation, enablement, and written description are tied to knowledge at the filing date. (Top) For three cases, claim language used in filed application compared to discovery after filing date. **(Bottom)** Outcomes of later-arising developments on filed claims.

Changing Classification
Phenetic (pre-1994): Genus *Clostridium* a 'dumping ground' for spore-forming anaerobes that do not reduce sulfate.
16S rRNA (1994): Division into phylogenetic *Clostridium* clusters I–XIX.
Genomic (2020): Circumscription of phylogenomic clusters *Clostridium_A*, *Clostridium_F*, *etc.*

Year	ATCC 29236	ATCC 27340	ATCC 35244
1984	*Clostridium coccoides* (T)	*Peptostreptococcus productus* (T)	*Peptostreptococcus productus*
2008	*Blautia coccoides* (T)	*Blautia producta* (T)	*Blautia producta*
2021	*Blautia coccoides* (T)	*Blautia coccoides* (by GTDB)	*Blautia celeris*
2025	*Blautia producta*	*Blautia producta* (T)	*Blautia celeris*

Table 2. Evolution of understanding that may occur in a 20-year patent term. (Left) Understanding of *"Clostridium"* has evolved with classification based on phenotype, to 16S rRNA, to genome. **(Right)** Three *Blautia* strains have had multiple non-overlapping names over 20 years.

Over the 20 years of a patent term, the specification remains fixed in time while biology moves forward. **Fig. 2**. For example, a given organism may be encompassed by multiple different names over 20 years. **Table 2, right**. As another, understanding of the meaning of a given term, such as a genus or species name, may change over 20 years. **Table 2, left**. While description or enablement of subject matter that does not exist is not required (*Hogan*, *Entresto*), applicants can be held to the interpretation of terms as evident from the specification *at the time of filing*. *Schering*, *Kopykake*, **Fig. 2**. Given the importance of the specification (*Phillips*) in claim interpretation, including controlling definitions grounded in the relevant taxonomic literature allows clarification of one's intent compared to disagreement in the field (*MIT*).

The written description and enablement requirements constrain claim scope, where claims encompass more than is adequately supported at the filing date. *Plant Genetic Systems*, *AbbVie*, *Juno*, *Amgen*, **Table 3**. But, multiple cases have distinguished invalid claims reciting broad, diverse categories from those reciting less diverse groups (*Vaeck*, *Martek Biosciences*) or taxa where the features underlying the invention's utility are conserved between the claimed and experimentally validated taxa. *BASF*, **Table 4**. Zones of discontinuity in genomic similarity circumscribing groups of different breadth (genomovars, phylogroups, species, higher taxa) may allow linking the scope claimed to the depth at which relevant features are conserved. **Fig. 3**.

Relevant Cases (developments after filing date)

In re Hogan, 559 F.2d 595 (C.C.P.A. 1977)
Schering Corp. v. Amgen Inc., 222 F.3d 1347 (Fed. Cir. 2000)
Kopykake Enterprises, Inc. v. Lucks Co., 264 F.3d 1377, 1380 (Fed. Cir. 2001)
In re Entresto, 125 F.4th 1090 (Fed. Cir. 2025)

Relevant Cases (claim construction at filing date)

Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*)
Ma. Inst. of Tech. v. Abacus Soft., 462 F.3d 1344 (Fed. Cir. 2006)

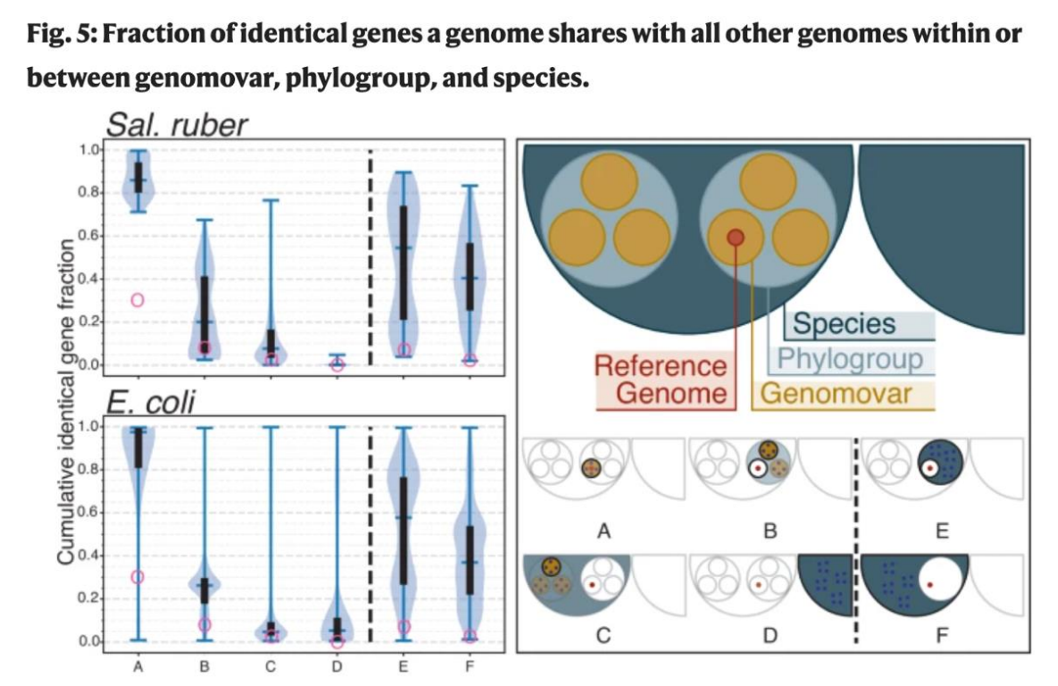
Consider: Genomes as Organismal Structure & Depth of Phenotypic Conservation

	Not Infringed	Infringed
Invalid	—	'Plant cell' claims encompassed monocots (corn). But, transforming monocots had not been successful at filing date. Invalid as not enabled.
Valid	'Plant' and 'seed' claims recited "capable of being transformed by *Agrobacterium*" to address enablement rejection. Enabled but not not infringed by monocot corn.	**Requires enablement commensurate with scope claimed at filing date.**

Table 3. In *Plant Genetic Systems*, the patentee was caught in the squeeze of having claims that either (i) encompassed the accused infringer but were invalid for lacking enablement; or (ii) enabled, but not broad enough to encompass the accused infringer.

Satisfied Enablement or Written Description	Lacking Enablement or Written Description	Contrast in Federal Circuit or Court of Customs and Patent Appeals Opinion
Brassica napus producing omega-3 long-chain polyunsaturated fatty acids	**"Plant"** instead of *B. napus*	*Arabidopsis thaliana* and *Brassica napus* shared relevant pathways and ability to produce precursor ALA v. leap from *A. thaliana* to '*any other plant*' is too great.
Genera *Anacystis* and *Synechocystis* expressing heterologous gene	**"Cyanobacteria"** instead of named genera	Prior art knowledge of one genus and working example with strain of other genus v. 'large, diverse and relatively poorly studied group' of bacteria
Order Thraustochytriales or *Thraustochytrium* and *Schiz ochytrium* in fermentation	**"Euryhaline microorganisms"** instead of named order or genera	22 species v. >10,000 species and 'a lot of unpredictability'

Table 4. Multiple Federal Circuit (or CCPA) cases have credited the conservation or lower diversity within narrower taxa, but disfavored claims reciting much broader taxa.



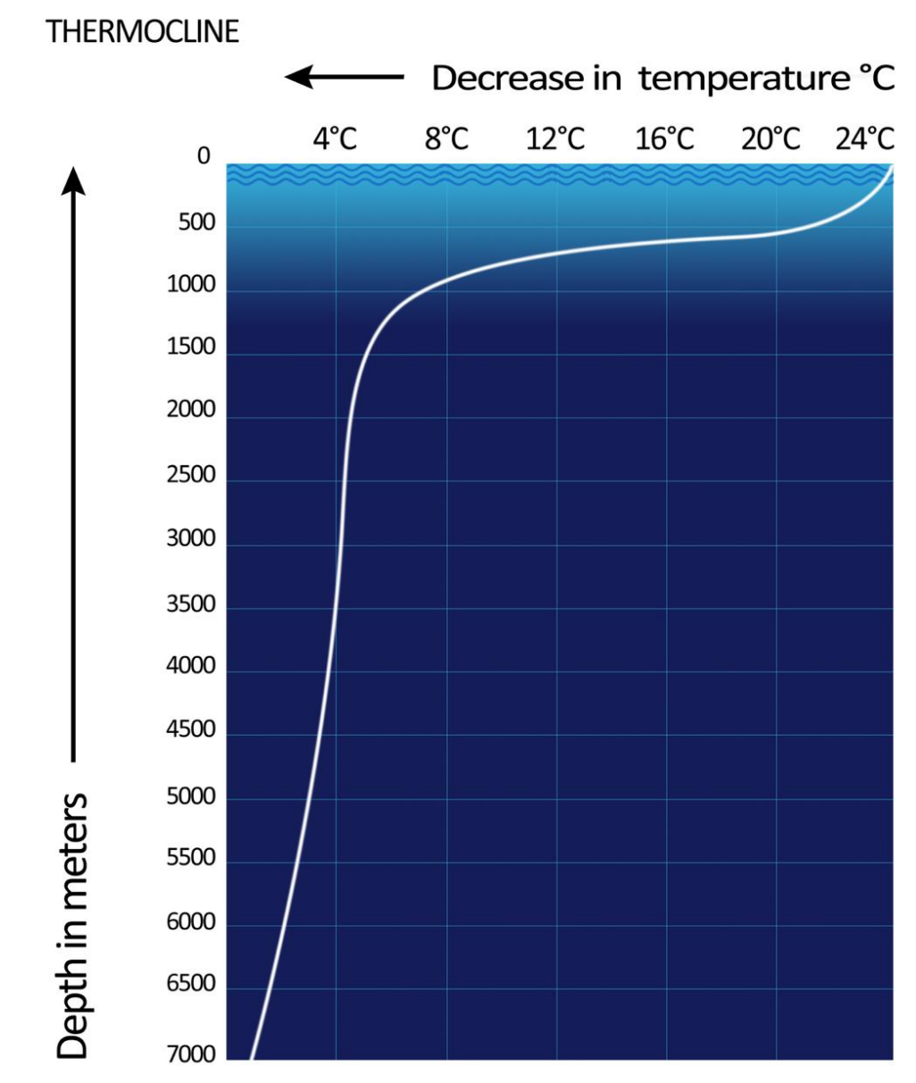


Fig. 3. (Above) Species, phylogroup, and genomovar circumscribing progressively similar groups of bacteria.
(Right) Thermocline, a steep gradient dividing: (0–500 m) a well-mixed zone keeping temperatures close to surface temperature, and (1000+ m) colder temperatures in calm, deep water.

Relevant Cases (policing claim scope)

Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335 (Fed. Cir. 2003)
AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285 (Fed. Cir. 2014)
Juno Therapeutics, Inc. v. Kite Pharma., 10 F.4th 1330 (Fed. Cir. 2021)
Amgen v. Sanofi, 598 U.S. 594 (2023)

Relevant Cases (diversity and conservation within taxa)

In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991)
Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363 (Fed. Cir. 2009)
BASF Plant Sci., LP v. Commonwealth Sci. & Indus. Rsch. Organisation, 28 F.4th 1247 (Fed. Cir. 2022)

Conrad RE *et al.*, Microbial species and intraspecies units exist and are maintained by ecological cohesiveness coupled to high homologous recombination, *Nat Commun*. 2024; 15(1):9906, Fig. 5. CC BY 4.0 license. https://creativecommons.org/licenses/by/4.0/
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