Insights: Alerts

Open-Ended Sequence Claims at CNIPA: What US Biotechnology Filers Have to Fix Before Filing

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CNIPA examiners routinely object to open-ended biological sequence language under Article 26.4 of the Chinese Patent Law and press applicants to closed-ended form.[1] US written description doctrine reaches a related question by a different route,[2] so a specification drafted only to US norms can leave its Chinese counterpart materially narrower. Every countermeasure that works is a disclosure, which means it has to be in the application on the day it is filed in the United States.

Key Takeaways

Do not assume a "comprising SEQ ID NO: X" claim survives in China. The open-ended family is comprising, containing, including and having; the closed family is consisting of and is. The concern examiners raise is that structure-activity relationships for sequences are not predictable, so an open end reaches countless unverified mutants. Such a claim can survive, and the fourth point below shows what that takes, but plan for the objection. The biotechnology amendments in the Guidelines revision effective January 1, 2026 address plant varieties and transgenic plants, not this.[1]

The fix is disclosure, and the deadline is US filing day. None of it can be argued away in Chinese prosecution and none of it can be added after the priority date. To preserve Chinese scope, the US application has to already carry: the six CDRs recited under Kabat, Chothia and IMGT; the shortest core sequence that carries the activity, plus an explicit length bound; enumerated rules for permitted terminal additions (signal peptide, affinity purification tag, fluorescent localization sequence, fusion linkers, and residues added to block hydrolysis, oxidation, amidation, deamidation or cyclodehydration); and mutant examples with activity data.

Put the sequence inside a larger conventional molecule where the science allows it. The objection attaches to a claim to the sequence per se. "A recombinant adeno-associated virus comprising the nucleotide sequence of SEQ ID NO: X" and "an antibody comprising heavy chain and light chain CDRs of SEQ ID NOs: 1 to 6" are generally accepted, because the surrounding framework is known and varies little. Design around the objection rather than litigating it.

One patentee has already shown what a specification has to say to keep "comprising." In CNIPA Invalidation Decision No. WX58530, a "comprising" double-stranded RNAi claim was maintained, as amended, against a support attack, because the specification systematically defined what "a strand comprising a sequence" means, the extent of mismatch the duplex tolerates, the overhang structures, and the

complementarity conditions. That definitional layer is what let the panel read it narrowly enough to be supported.[3]

Separately, an Article 5 legality attack turns on the purpose of the disclosure, not on a regulated step in making it. The Supreme People's Court affirmed a Sphingomonas engineering-strain patent against a challenge that using chloramphenicol and kanamycin to build the strain violated the Food Safety Law. An invention-creation contrary to law, the Court stated, is one whose own purpose contravenes the law; antibiotic selection was conventional screening, the fermentation product was not specific to food use, and a skilled person could remove non-compliant substances by routine purification.[4] Worth knowing for ag-bio, synthetic biology and food-tech clients. US law has no general morality bar.[2]

We will continue to monitor CNIPA examination practice in this area and will report developments. Please contact us if you would like pending biotechnology specifications reviewed against these requirements before filing.

Footnotes

[1] Patent Law of the People's Republic of China, art. 26, para. 4 (support); see also art. 26, para. 3 (sufficiency) and art. 5 (inventions contrary to law or social morality). The Part II Chapter 10 amendments in the Guidelines revision effective Jan. 1, 2026 (CNIPA Order No. 84) address wild plants, the plant variety criteria and transgenic plants at sections 9.1.2.3 and 9.1.2.4; none addresses the support standard for biological sequences.

[2] MPEP 2163 poses the claim "A gene comprising SEQ ID NO:1" and observes that although the sequence is fully disclosed, "there may be insufficient description of other structures embraced by the claim (e.g., promoters, enhancers, coding regions, and other regulatory elements)," which is a written description question about the added structure rather than a per se defect; *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023), polices functionally claimed genus breadth through enablement. On art. 5, the moral-utility doctrine was rejected in *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364 (Fed. Cir. 1999); the narrow statutory exception is AIA sec. 33(a), Pub. L. 112-29 (2011), barring a claim directed to or encompassing a human organism.

[3] CNIPA Invalidation Decision No. WX58530 (Sept. 15, 2022), addressing ZL 201580072874.0 (Alnylam Pharmaceuticals, Inc.).

[4] (2024) Final, Administration, IP, No. 1241 (Sup. People's Ct. May 30, 2025), affirming Beijing Intellectual Property Court (2024) Jing 73 Xing Chu No. 1034 and upholding CNIPA Invalidation Decision No. 563236 (Oct. 23, 2023) on patent 2019113742**.0. The Court stated that an invention-creation contrary to law under art. 5, para. 1 is one whose own purpose contravenes the law. The Supreme People's Court designated the case in its Annual Report on the Application of Law in Intellectual Property Cases (2025), item 8, for a separate holding on sufficiency of disclosure. Compare Implementing Regulations of the Patent Law, rule 10: an invention-creation contrary to law does not include one whose exploitation alone is prohibited by law.

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