How to patent targeted therapy pharmaceuticals in China

Time：Aug 07
2024

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Precis: The CNIPA's examination practice when it comes to targeted therapy drugs is tightening, with examiners increasingly inclined to reject claims. Against this backdrop, it is crucial for patent applicants to submit diverse examples to secure a satisfactory scope of protection and build a solid case.

Targeted cancer therapies involve agents that directly or indirectly attack a specific genetic biomarker found in a given cancer. Examples of targeted drugs include small molecules, antibodies, polypeptides, antibody-drug conjugates and nucleic acids, among others.

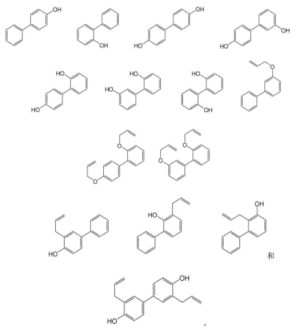
For newly discovered biomarkers associated with a certain cancer, it is typical to file for a patent application over targeted therapy drugs, apart from when it comes to diagnostic use. In China, claims of such pharmaceutical use are drafted as Swiss-type claims, which often read: "agents that [inhibit a target] in the preparation of a medicament for the treatment of [a certain disease]."

Over the years, the China National Intellectual Property Administration (CNIPA)'s examination practice on this issue has shifted. In most cases, the CNIPA used to allow the pharmaceutical use of biomarker-derived agents, which were drafted to cover a broad scope of protection, as long as the pharmaceutical effect of the target is new. This led to the smooth granting of patents in the last 10 years with biomarker-related features, broadly defined as 'inhibitor', 'antagonist' or 'agonist'. Although some were further defined with functional features, most had a reasonably satisfactory protection scope. See below for some examples.

Application number	Granted claim 1	Grant date
201810265974.0	Use of VCP inhibitor in the preparation of an anti-tumor synergist or a drug-resistance reversal agent for oncolytic virus, wherein the oncolytic virus is the M1 virus.	2 October 2018
201710478154.5	Use of an miR-3648 expression inhibitor in the preparation of medicaments for the inhibition of bladder cancer metastasis.	27 March 2020
201710854229.5	Use of an agent inhibiting the Myosin1b protein expression in the preparation of medicaments for the treatment of cervical cancer.	2 February 2021
CN201680050962.5	Use of the Allergin-1 antagonist in the preparation of medicaments for enhancing immunity and suppression of progress or recurrence of cancer, wherein the Allergin-1 antagonist suppresses immunosuppressive intracellular signalling of Allergin-1.	12 November 2021

In the last two years, the examination criteria over targeted therapy drugs have been gradually tightened. In general, examiners are increasingly inclined to reject the claim on the ground that target-related features are devoid of support from the specification. See below for some recent examples of applications, which have been amended to overcome rejection.

Application number	Granted claim 1	Original claim 1	Grant date
CN201880070859.6	Use of an antibody that is capable of binding and inhibiting the ATPase activity combined with a platinum agent in the preparation of medicaments for treating cancer, wherein the antibody is made up of: • an HCDR1 comprising amino-acid sequence DYNMH (SEQ ID NO: 5); • an HCDR2 comprising amino-acid sequence YIVPLNGGSTFNQKFKG (SEQ ID NO: 6); • an HCDR3 comprising amino-acid sequence GGTRFAY (SEQ ID NO: 7); • an LCDR1 comprising amino-acid sequence RASESVDNFGVSFMY (SEQ ID NO: 8); • an LCDR2 region comprising amino-acid sequence GASNQGS (SEQ ID NO: 9); and • an LCDR3 region comprising amino-acid sequence QQTKEVPYT (SEQ ID NO: 10)	An antibody that is capable of binding and inhibiting the ATPase activity of the human CD39 (NTPDasel) protein for use in treating a tumor. The treatment comprises administering an effective amount of an antibody that is capable of binding and inhibiting the ATPase activity of CD39 in the presence of ATP, and an agent or treatment that induces the extracellular release of ATP from tumor cells.	20 February 2024

	(SEQ ID NO: 10). This could be used to treat ovarian cancer, stomach or esophageal cancer, lung cancer, colon cancer, head and neck cancer, and platinum-resistant cancer.		
201810865178.0	Pharmaceutical composition for use in the prevention or treatment of pancreatic ductal intraepithelial neoplasia, wherein the composition is capable of reducing or inhibiting: • the biological activity of BCAT2; or • the expression of a gene encoding BCAT2. The pharmaceutical composition comprises an shRNA targeting the BCAT2 gene, wherein the sequence of said shRNA is as shown in SEQ ID NO:1-6, and the composition further comprises a pharmaceutical excipient.	Pharmaceutical composition for the prevention or treatment of pancreatic cancer, wherein the composition is capable of reducing or inhibiting: • the biological activity of BCAT2; or • the expression of a gene encoding BCAT2.	16 April 2024
201980091497.3	Use of an NFkB inhibitor and adjuvant in the preparation of vaccines, and the NFkB inhibitor is selected from: 	A method for vaccinating a subject, which comprises administering an NFkB inhibitor and an adjuvant to the subject.	9 July 2024

On top of formal office actions, examiners are increasingly resorting to phone calls with patent attorneys to propose amendments that often further limit the claims.

In order to secure a satisfactory scope of protection, applicants seeking to patent drugs for biomarker-targeted therapy should submit diverse examples (eg, nucleic acid molecules, antibodies and small molecular) to build a solid case.

Further, if an applicant fails to secure a satisfactory scope of protection during the substantive examination process, it would be worth trying the reexamination procedure to reverse the initial decision, or to at least regain some lost ground. For example, in decision 1F422128, which was issued on 22 April 2023, the CNIPA's reexamination board allowed for a more reasonable scope than the examiner in the substantive examination. Of course, applicants must take into account the breadth of the specification in assessing the viability of reexamination. For example, specifications with mere experimental data of small-molecular examples would be highly insufficient to support a reasonable scope.

Finally, if the pharmaceutical use of a targeted drug cannot be granted with satisfactory scope, another option is to claim for a drug screening method.