



## Annual EU-China Forum 2023: Comparative Approach to Judiciary Procedures: pemetrexed 中欧知识产权司法论坛：培美曲塞案

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Unified Patent Court  
Einheitliches Patentgericht  
Jurisdiction unifiée du brevet

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## Pemetrexed /// 培美曲塞

- Claim 1: use of disodium salt of pemetrexed in manufacture of a medicament to treat tumors in combination with vitamin B12 (Swiss type claim) /// 权利要求一：使用培美曲塞二钠制备某款与维生素B12联用的肿瘤治疗药物（瑞士型专利要求）
- Invention: antifolates (example 1= pemetrexed disodium) are toxic and surprisingly found that administration with vitamin B12 can lower toxicity but does not affect therapeutic efficacy (paragraph [0005] patent) /// 发明：叶酸拮抗剂（实施例一 = 培美曲塞二钠）具有毒性，但研究者偶然发现，与维生素B12联用可以在不影响疗效的情况下降低毒性（专利第[0005]段）。

## Pemetrexed /// 培美曲塞

- Infringement: combination therapy of dipotassium salt of pemetrexed with vitamin B12 /// 侵权：培美曲塞二钾与维生素B12联用
- Question: is pemetrexed dipotassium equivalent to pemetrexed disodium? /// 问题：培美曲塞二钾与培美曲塞二钠等效吗？

## Pemetrexed /// 培美曲塞

- More fundamental question: patentee writes his monopoly and if he chooses words restricting his monopoly, he should face the consequences. If not, when not? /// 更基本的问题：独占权范围由专利权人自行定义。因其自身用词导致独占权范围受限，理应由专利权人承担后果。但是，在哪些情形下，专利权人不应承担后果？

## Claim construction - law /// 权利要求的建构——法规

- Art. 69 EPC: The extent of protection conferred by a European patent shall be determined by the claims. Nevertheless the description and drawings shall be used to interpret the claims. /// 欧洲专利公约（EPC）第69条：欧洲专利所授予的保护范围取决于权利要求的内容。然而，说明书和附图应当用以解释权利要求。

## Claim construction – law /// 权利要求的建构——法规 Protocol of interpretation Art. 69 EPC /// 解释规则（EPC第69条）

- Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. /// 第69条不应被解释为欧洲专利所授予的保护范围严格取决于权利要求的字面内容，而说明书和附图仅用于解决权利要求中发现的歧义。

**Claim construction – law /// 权利要求的建构——法规**  
**Protocol of interpretation Art. 69 EPC /// 解释规则（EPC第69条）**

- **Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. /// 也不应将其解释为权利要求仅用作指引，实际保护范围以专利权人所估量的、本领域技术人员通过说明书和附图推断所得的范围为界。**



**Claim construction – law /// 权利要求的建构——法规**  
**Protocol of interpretation Art. 69 EPC /// 解释规则 (EPC第69条)**

- Find a balance between a fair protection for the patentee with a reasonable degree of certainty for third parties. /// 在对专利权人的公平保护和对第三方的合理确定性之间寻求平衡。
- Paragraph 2: due account of equivalent elements /// 第2款：对等同要素作适当考虑
- Equally applies in the UPC (Art. 24(1) UPCA) /// 同样适用于统一专利法院（统一专利法院协议第24条第1款）

**Claim construction – law /// 权利要求的建构——法规**  
**Protocol of interpretation Art. 69 EPC /// 解释规则 (EPC第69条)**

- Reason for not too literal: hard to know when you apply for a patent what competitors might do to circumvent while still taking advantage of the invention /// 不太字面的原因：申请专利时，很难预判竞争对手会采取什么方法绕开专利限制，继续利用有关发明。

## NL claim construction /// 权利要求的建构（荷兰）

- The claims are the starting point, but will always (not only in case of ambiguity) be interpreted in light of the description and drawings /// 权利要求是解释的起点，但无论是否存在模糊性，解释都要考虑说明书和附图
  - The description and drawings can be used to widen the literal wording of the claims but also to limit it DSC Medinol/Abbott /// 说明书和附图可以用于延展权利要求的字面含义，也可用于限制权利要求（美国联邦地区法院，Medinol诉雅培案）

## NL claim construction /// 权利要求的建构 (荷兰)

- The court may take into account several viewpoints: /// 法院可以考虑以下几点:
  - Inventive concept behind the invention /// 发明背后的创造性概念
  - Fair protection patentee /// 对专利权人的公平保护
  - Reasonable certainty third parties /// 对第三方的合理确定性
  - Prosecution file (to the detriment of the patentee) /// (对专利权人不利的) 专利申请记录

## Infringement analysis in NL /// 侵权分析（荷兰）

- Two step approach: /// 两步法:
  1. Literal infringement /// 1、对侵权的字面分析  
i.e. claim construction, so balancing fair protection and reasonable certainty third parties or  
即权利要求的建构，公平保护和第三方合理确定性之间的平衡，或
  2. Equivalence /// 2、等同原则

## Infringement analysis in NL /// 侵权分析（荷兰）

- Equivalence, 4 requirements (see e.g. Pemetrexed and here): /// 等同原则，4项要求（参见培美曲塞案和本页解释）：
  1. Technical equivalence /// 技术等同
    - does element solve (essentially) same problem and perform (essentially) same function) /// 技术特征是否（本质上）解决相同问题，（本质上）实现相同功能？
  2. Fair protection patentee /// 公平保护专利权人
    - contribution to the art /// 技术贡献
    - obvious from patent how to apply equivalent element (at time of infringement) /// 从专利中，是否容易得出等同技术特征（在侵权时）的应用方法

## Infringement analysis in NL /// 侵权分析（荷兰）

- Equivalence, 4 requirements (see e.g. Pemetrexed and here): /// 等同原则，4项要求（参见培美曲塞和本页）：
  3. Reasonable legal certainty third parties /// 3、第三方合理法律确定性
    - does skilled person understand from patent that scope of invention is broader /// 本领域技术人员是否认为发明范围大于专利范围
  4. Equivalent still new and inventive over prior art /// 4、等同技术与现有技术比较仍然具有新颖性和创造性
    - Otherwise Gillette/Formstein defence /// 否则，“吉列”/“成型地砖”抗辩

## Pemetrexed cont'd /// 培美曲塞（续）

- No literal infringement, but equivalent? /// 不构成字面意义上的侵权行为，但适用等同原则？
  - 1. Technically equivalent: yes, pemetrexed anion has therapeutic effect, irrespective of salt form (kation) /// 1. 技术等同：是。培美曲塞阴离子产生治疗作用，与盐型（阳离子）无关。
  - 2. Fair protection patentee: yes, disodium has function of providing pemetrexed anions so other kations/salts would do this as well and easy to envisage dipotassium also. /// 公平保护专利权人：是。二钠盐可以作为培美曲塞阴离子的释药载体，其他阳离子/盐型同样可以，联想到二钾盐较为容易。
  - 3. reasonable certainty 3rd parties: yes, teaching of patent is clearly more broadly applicable to other pemetrexed salts. No good reason to restrict, also not in prosecution file /// 第三方合理法律确定性：是。专利描述显然适用于其他盐型。没有限制的正当理由，专利申请记录中也未体现。
  - 4. equivalent still new and inventive: yes, no argumants forwarded /// 4. 等同产品仍然具有新颖性和创造性：是。但未作为论据。



## Relevance of amended description /// 说明书的修订

- claim limitation because of 123(2) EPC (added matter) -> equivalence still possible /// 由于欧洲专利公约第123条第2款对权利要求（新增内容）的限制 -> 仍有可能构成等同
  - EPO disregards equivalents when assessing added matter /// 评估新增内容时，欧专局不考虑等同原则
  - Pemetrexed-case: claim limited to disodium salt because of added matter objection -> still equivalence possible (infringement and added matter different legal concepts) /// 培美曲塞案：由于新增内容抗辩，权利要求仅限于二钠盐 -> 仍有可能构成等同（专利侵权和新增内容属于不同的法律概念）

## Other European countries /// 其他欧洲国家

- Two step approach also in UK (Lilly/Actavis, para 54) and in continental Europe /// 英国（礼来诉Actavis，第54段）和欧洲大陆都采用两步法
- Also doctrine of equivalence in UK, FR, DE, IT and other UPC MS /// 在英国、法国、德国、意大利和其他统一专利协议缔约成员国均采用等同原则
- Differences exist between UPC MS and UK /// 统一专利协议缔约成员国和英国之间存在差异
- but similar outcomes, common threads: /// 但异曲同工：
  - (i) technical equivalence (same function/effect) /// (I) 技术等同（相同功能/效果）
  - (ii) that obvious from patent equivalent would have same effect /// (II) 从专利易得：等同技术特征实现相同效果
  - (iii) strict compliance /// (三) 严格相符
  - (iv) equivalent should be new/inventive over prior art (Formstein) /// (IV) 对等同技术相较现有技术的新颖性/创造性提出要求（“成型地砖”抗辩）

- Thank you for your attention!  
感谢聆听!