SECOND MEDICAL USE PATENTS PART 2: VERIFYING VALIDITY

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QUESTION 1:

VALIDITY CHALLENGES TO SECOND MEDICAL USE PATENTS IN YOUR JURISDICTION

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VALIDITY CHALLENGES TO SECOND MEDICAL USE PATENTS

Canada	China	Russia	UK
• Novelty • Inventiveness • Sufficiency • Utility • Overbreadth	• Novelty • Inventiveness • Sufficiency	• Novelty • Inventiveness • Industrial use • Sufficiency	• Novelty • Inventiveness • Industrial use • Sufficiency • Added matter
• Be wary of the squeeze between anticipation and obviousness versus utility and overbreadth	• There is an emphasis on data in order to meet the sufficiency requirement although this is becoming more relaxed	• The introduction of sufficiency is a recent development. Novelty and inventive step are the most critical grounds in practice	• Attacks often use a squeeze between inventiveness and sufficiency

QUESTION 2:

APPROACH TO NOVELTY AND INVENTIVENESS CHALLENEGS TO SECOND MEDICAL USE PATENTS?

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THE NOVELTY AND INVENTIVENESS OF SECOND MEDICAL USE CLAIMS

Canada	China	Russia	UK
• Two notable current issues: • (1) is the "result" part of the claimed "subject matter"? • (2) the experimental use exemption	• Swiss type claims only • The claim must affect the method of manufacturing the drug • Dosage regimen is the doctors' choice	• Formal approach for novelty and inventiveness • Overcoming the inventive step is becoming more difficult	• Novelty – clear and unambiguous disclosure of use and the therapeutic effect? • Inventiveness – Courts use 4 step Pozolli approach • "Obvious to try" – can be problematic

QUESTION 3:

WHAT IS REQUIRED FOR SUFFICIENCY OF A SECOND MEDICAL USE PATENT?

Requirement for plausibility?

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SUFFICIENCY OF A SECOND MEDICAL USE PATENT

Canada	China	Russia	UK

• Plausibility-type arguments are dealt with via utility/ overbreadth attacks
 	
• Limited to pre-filing data; no requirement to disclose data except (possibly) if useful only via prediction
	• Historically, efficacy data must be provided to meet sufficiency requirements at the point of filing
	
	• Since 2017 it is possible to provide post-filing data
	
	• New guidelines issued December 2020
		• Sufficiency used to be a part of the inventiveness and industrial applicability requirement
		
		• Patents cannot include a technical effect that was not originally disclosed
			• The specification must allow the skilled person to carry out the patent.
			
			• Three types:
			  • Classical insufficiency
			  • Breadth of claim (most common)
			  • Ambiguity
			
			• “Plausibility” often key consideration

QUESTION 4:

VALIDITY CONCERNS FOR DOSING REGIME PATENTS

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QUESTIONS?

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