

O GOWLING WLG



QUESTION 1:

VALIDITY CHALLENGES TO SECOND MEDICAL USE PATENTS IN YOUR JURISDICTION



VALIDITY CHALLENGES TO SECOND MEDICAL USE PATENTS

Canada	China	Russia	UK
NoveltyInventivenessSufficiencyUtilityOverbreadth	NoveltyInventivenessSufficiency	NoveltyInventivenessIndustrial useSufficiency	NoveltyInventivenessIndustrial useSufficiencyAdded 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?



THE NOVELTY AND INVENTIVENESS OF SECOND MEDICAL USE CLAIMS

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





QUESTION 3:

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

REQUIREMENT FOR PLAUSIBILITY?



SUFFICIENCY OF A SECOND MEDICAL USE PATENT

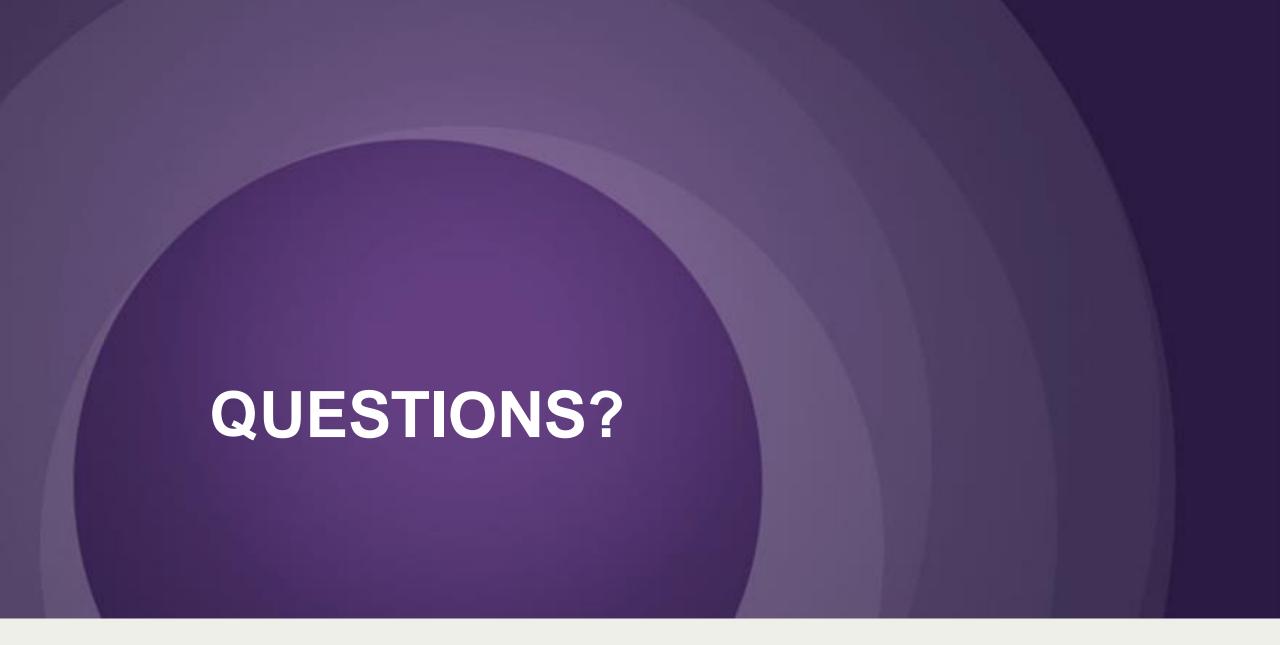
Canada	China	Russia	UK
 Plausibility-type arguments are dealt with via utility/ overbreadth attacks 	 Historically, efficacy data must be provided to meet sufficiency requirements at the point of filing 	 Sufficiency used to be a part of the inventiveness and industrial applicability requirement 	 The specification must allow the skilled person to carry out the patent. Three types:
 Limited to pre-filing data; no requirement to disclose data except (possibly) if useful only via prediction 	 Since 2017 it is possible to provide post-filing data New guidelines issued December 2020 	Patents cannot include a technical effect that was not originally disclosed	 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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FOR MORE INFORMATION, PLEASE CONTACT SHANNON.WADSWORTH@GOWLINGWLG.COM

