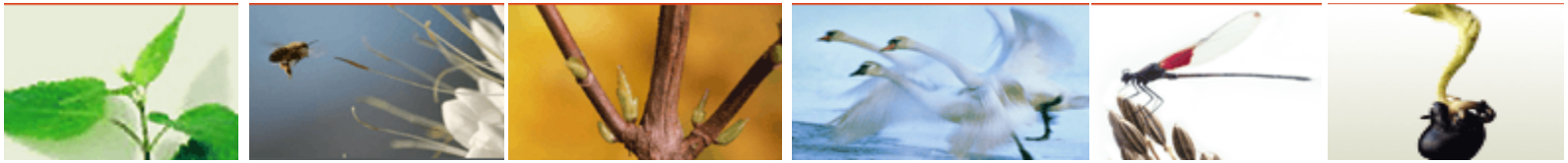
Revival of Reach Through Claims

(U.S. Perspective - Did They Ever Go Away?)



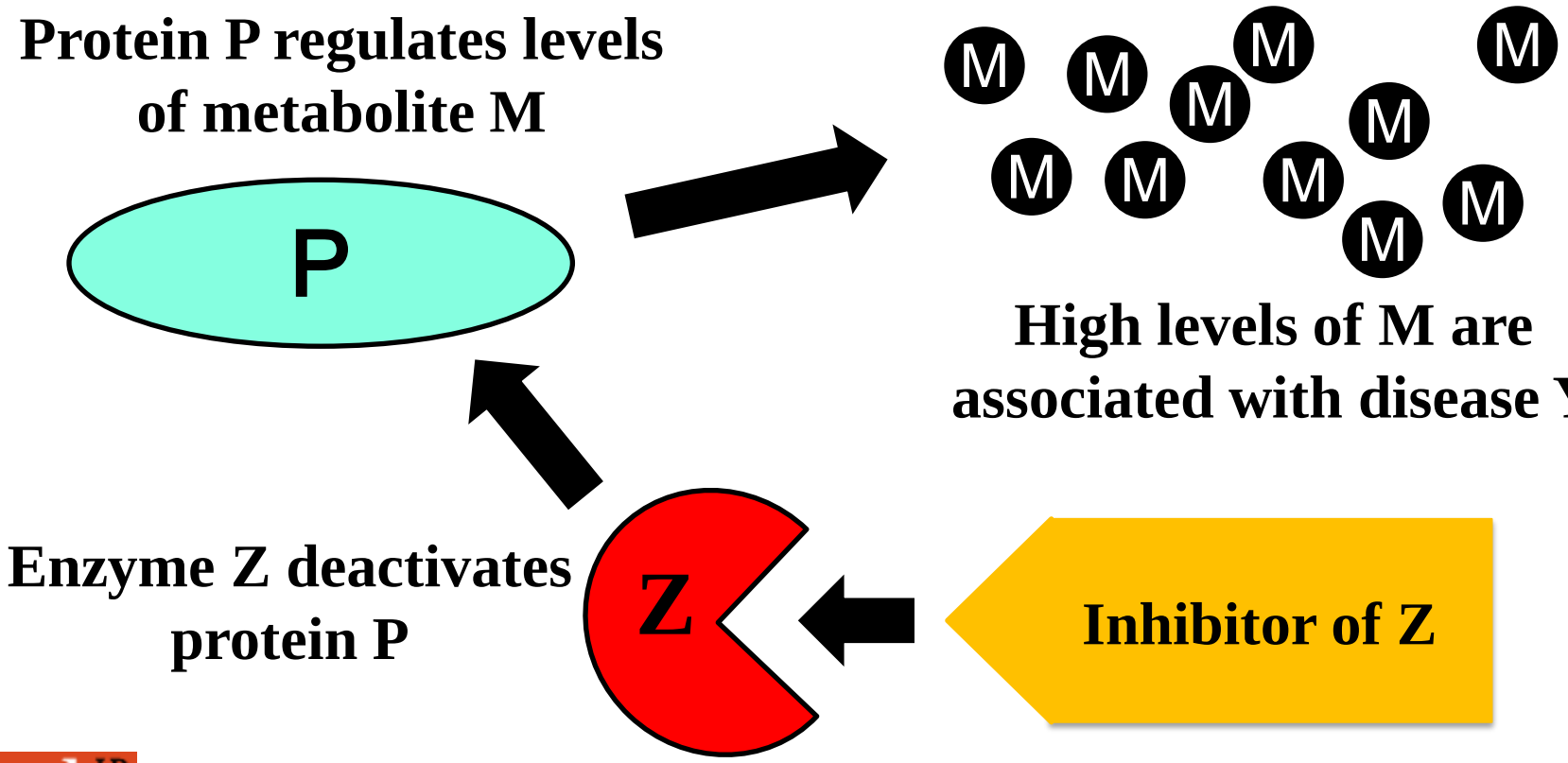
Karl R. Hermanns
Seed IP Law Group, PLLC

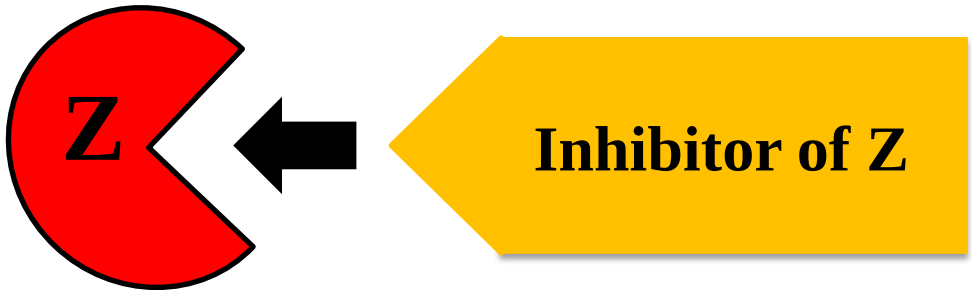
November 7, 2014
Barcelona, Spain

FICPI – 15th Open Forum
International Federation of Intellectual Property Attorneys

Claim Scenario

"A method for lowering levels of endogenous metabolite M in a patient with disease Y by administering an inhibitor of enzyme Z."





Can claim recite administering an "**Inhibitor of Z**"?

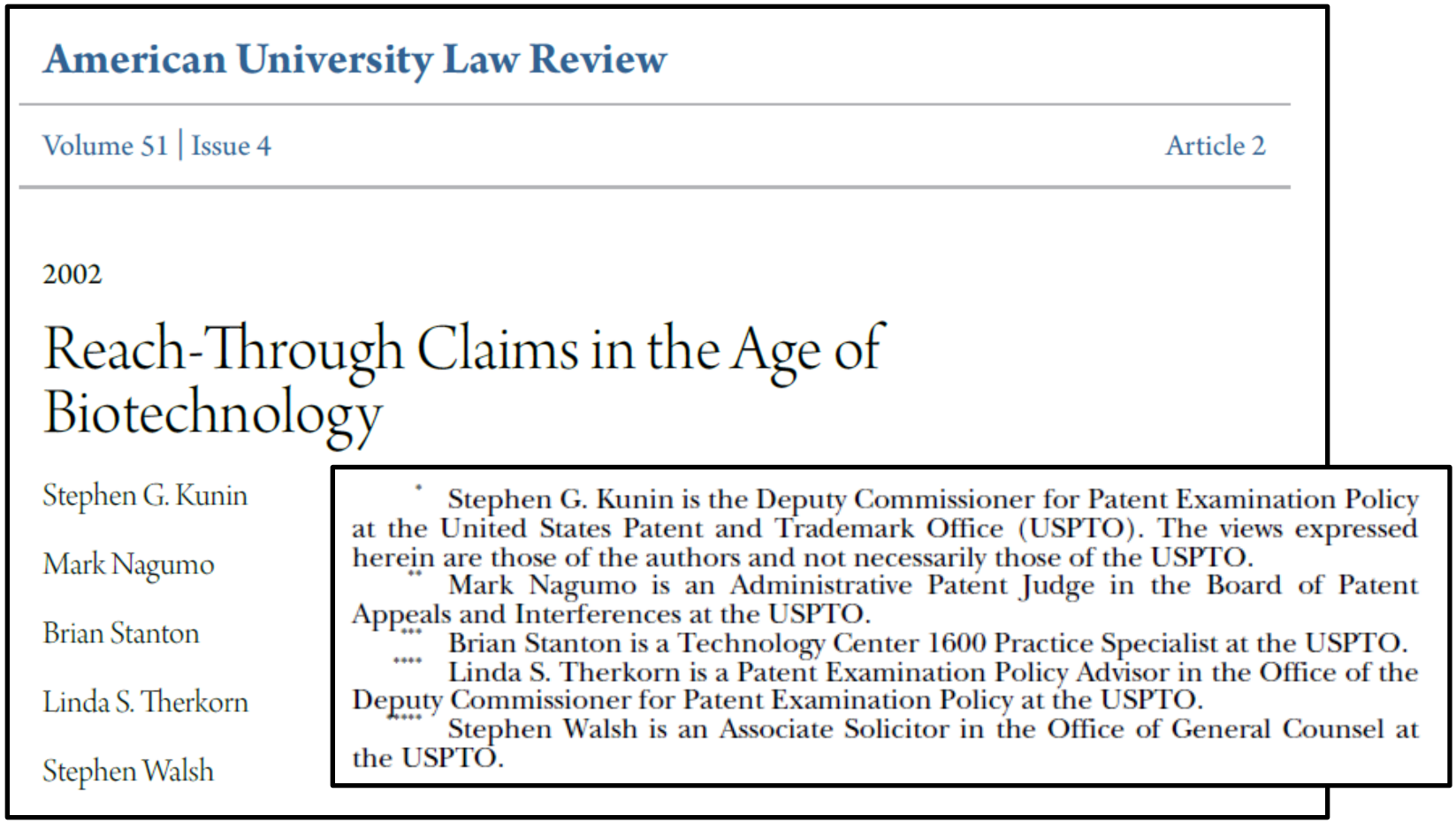
Reach-Through Claim
Encompasses not only what is exemplified in the specification, but any "**inhibitor of Z**" later discovered and used for this purpose

US Requirements

- Utility
  - Specific, substantial and credible utility
- Sufficiency of Specification
  - Enablement
    - Teach one skilled in the art how to make and use the full scope of the claimed subject matter without undue experimentation
  - Written Description
    - Possession by the inventor of the claimed subject matter at the time of filing

Do reach-through claims necessarily fail to meet these requirements?

Some think so …



American University Law Review

Volume 51 | Issue 4 Article 2

2002

Reach-Through Claims in the Age of Biotechnology

Stephen G. Kunin

Mark Nagumo

Brian Stanton

Linda S. Therkorn

Stephen Walsh

* Stephen G. Kunin is the Deputy Commissioner for Patent Examination Policy at the United States Patent and Trademark Office (USPTO). The views expressed herein are those of the authors and not necessarily those of the USPTO.

** Mark Nagumo is an Administrative Patent Judge in the Board of Patent Appeals and Interferences at the USPTO.

*** Brian Stanton is a Technology Center 1600 Practice Specialist at the USPTO.

**** Linda S. Therkorn is a Patent Examination Policy Advisor in the Office of the Deputy Commissioner for Patent Examination Policy at the USPTO.

***** Stephen Walsh is an Associate Solicitor in the Office of General Counsel at the USPTO.

Reach-through claims are not patentable because they do not satisfy the requisite disclosure criteria for obtaining a patent, which is found in the requirements of 35 U.S.C. §§ 101 and 112, ¶ 1. The reach-through invention does not exist as of the filing date of the application for patent. By its nature, the inventor cannot describe it in such terms that one skilled in the art would have recognized that the inventor had possession of the claimed subject matter, nor can the inventor provide sufficient teachings of how to make or use the reach-through invention. Indeed, the inventor cannot provide a sufficient disclosure so others may know what it is that they are excluded from making, using, selling, offering for sale, or importing into the United States.[142]

Stephin G. Kunin, et al, *Reach-Through Claims in the Age of Biotechnology*, American University Law Review, 51:609 (2002), page 637

MPEP doesn't say this …

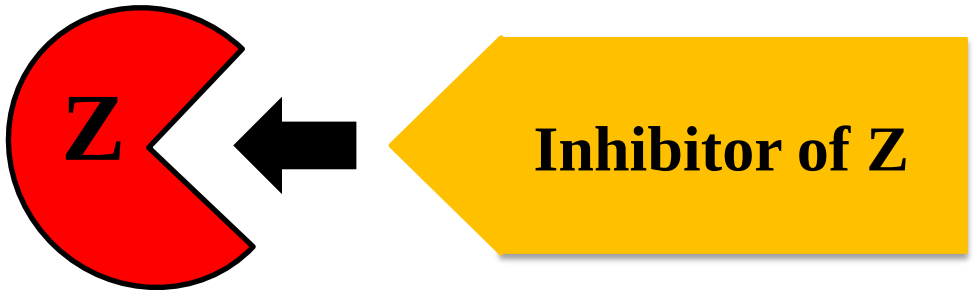
- 2173.05(g)
  - A claim term is functional when it recites a feature "by what it does rather than by what it is"
  - There is nothing inherently wrong with defining some part of an invention in functional terms
  - Functional language does not, in and of itself, render a claim improper

- 2164.03
  - The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every possible species is not required
  - In applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide adequate basis to support generic claims
    - because it is not obvious from the disclosure of one species, what other species will work

How does the USPTO treat reach-through claims?

But first, a disclaimer …

- Scenario involves a method claim
  - It is not a claim to the product itself
    - "An inhibitor of Z"
  - Or a claim to a product identified by screening
    - "An inhibitor of Z identified by screening method X."
- Such product claims (in my opinion) …
  - Are more likely to fail for lack of enablement and/or written description
    - and more difficult to get allowed by the USPTO



Scenario 1:

NO Inhibitors of Z are known

→ Zero is not enough

Univ. of Rochester v. Searle (CAFC 2002)

See also, Ariad Pharmaceuticals v. Eli Lilly (CAFC 2010)

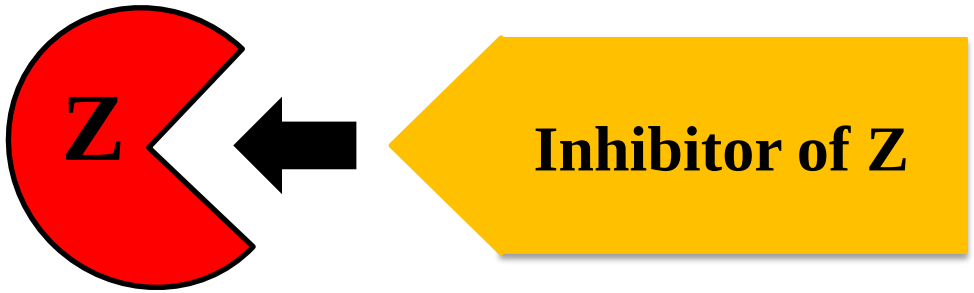
Univ. of Rochester

- US Patent 6,048,850
  - "A method of selectively inhibiting PGHS-2 (Cox-2) activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment"

➢ No representative compounds were disclosed having such Cox-2 selectivity over PGHS-1 (Cox-1)

Univ. of Rochester

- Without any guidance to steer the skilled practitioner toward compounds that can be used to carry out the claimed methods …
  - Claims failed for lack of written description
- Lack of enablement was not addressed
  - Considered moot in view of invalidity based on lack of written description



Scenario 2:

FOUR Inhibitors of Z are known

(but for different purposes)

→ Is four enough?

Patent	Known inhibitors	Exemplified inhibitors	Claim
6,303,661 Granted 10/16/2001	4	1	A method for lowering elevated blood glucose levels in mammals resulting from food intake comprising administering at least one oral administration of a therapeutically effective amount of at least one inhibitor of Dipeptidyl Peptidase (DP IV) or of DP IV-like enzyme activity.
7,863,429* Issued 1/4/2011	3	1	A method for treating psoriasis, the method comprising: administering an effective amount of an inhibitor of integrin linked kinase (ILK) to a psoriatic lesion, wherein expression of ILK in psoriatic tissue correlates with severity of disease, and said ILK inhibitor is a small organic molecule that inhibits ILK activity.
8,084,422 Issued 12/27/2011	>6	1	A method for treating insulin resistance comprising administering a subject in need thereof with a selective inhibitor of cannabinoid type 2 (CB2) receptor activity, wherein said selective inhibitor of CB2 receptor activity is a small organic molecule.
8,168,199* Issued 5/1/2012	5	1	A method of treating schizophrenia or depression, the method comprising administering to a subject in need thereof, a therapeutically effective amount of a composition comprising an inhibitor of dipeptidyl peptidase IV (DPIV), or a pharmaceutically acceptable salt thereof.
8,491,897 Issued 7/23/2013	3 (2 monoclonal, 1 polyclonal)	3 (2 monoclonal, 1 polyclonal)	A method of treating neuropathic pain in an individual comprising administering to an individual having neuropathic pain an effective amount of, an antibody that binds to a thrombospondin and blocks the interaction between the thrombospondin and one or more calcium channel subunits selected from the group consisting of α2δ1, α2δ2, α2δ3, and α2δ4.

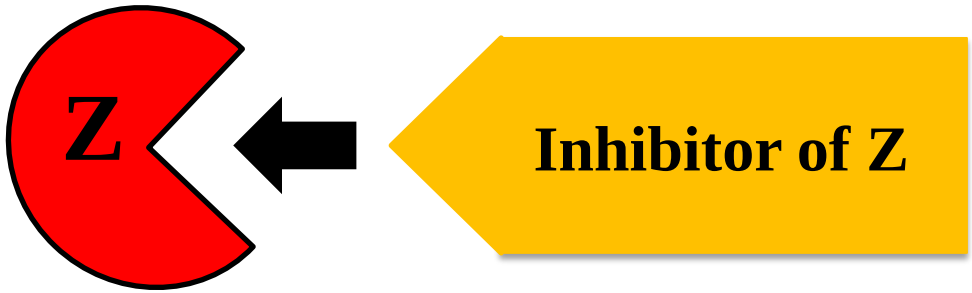
*overcame §112 rejection at board level

(12) **United States Patent**
Dedhar et al.

(10) **Patent No.: US 7,863,429 B2**
(45) **Date of Patent: Jan. 4, 2011**

> **1**. A method for treating psoriasis, the method comprising: administering an effective amount of an inhibitor of integrin linked kinase (ILK) to a psoriatic lesion, wherein expression of ILK in psoriatic tissue correlates with severity of disease, and said ILK inhibitor is a small organic molecule that inhibits ILK activity.

- Three known compounds disclosed
  - only one was exemplified
- Claim rejected by Examiner
  - lack of enablement
- PTAB reversed
  - "Enablement is not precluded by the necessity for some experimentation such as routine screening."



Scenario 2:

FOUR Inhibitors of Z are known

(all for different purposes)

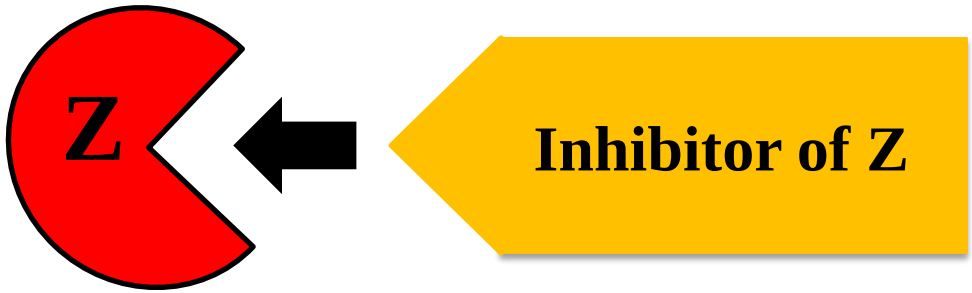
Is four enough?

Should be OK

Provided that you teach …

Inhibitor of Z yields the expected result

- Appropriate mechanistic support
  - High levels of metabolite M are associate with disease condition Y
  - Protein P regulates levels of M
  - Enzyme Z deactivates P
  - Inhibitor Z inhibits activity of Z on P
- Plus representative examples of inhibitor Z demonstrating the expected result
  - Identified by specific screening method



Scenario 3:

TWENTY-FIVE Inhibitors of Z

(20 known, but for different purposes)

<u>Is 25 enough?</u>

Even Better!

Post-Filing Data?

- Under U.S. practice, post filing data may be presented during prosecution
  - Can be helpful to secure issuance of claims
- However, such data cannot cure insufficient specification
  - E.g., post filing data can show that one skilled in the art can make/use the invention as taught in the specification as originally filed
    - Thus, specification enabling at time of filing

Do such reach-through claims survive litigation in the United States?

Wyeth v. Abbott (CAFC 2013)

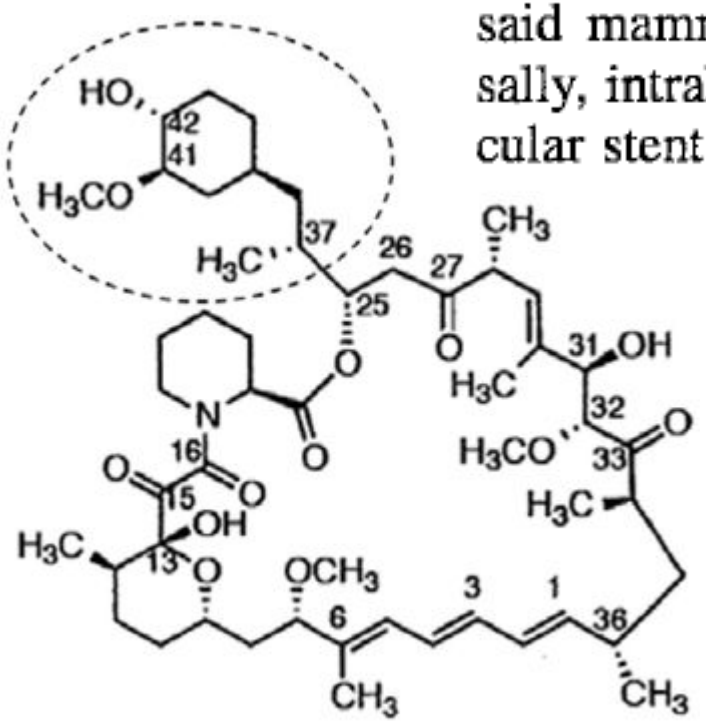
United States Patent [19]

Morris et al.

[11] **Patent Number: 5,516,781**

[45] **Date of Patent: *May 14, 1996**

1. A method of treating restenosis in a mammal resulting from said mammal undergoing a percutaneous transluminal coronary angioplasty procedure which comprises administering an antirestenosis effective amount of rapamycin to said mammal orally, parenterally, intravascularly, intranasally, intrabronchially, transdermally, rectally, or via a vascular stent impregnated with rapamycin.



Sirolimus (a known rapamycin) was the only compound disclosed

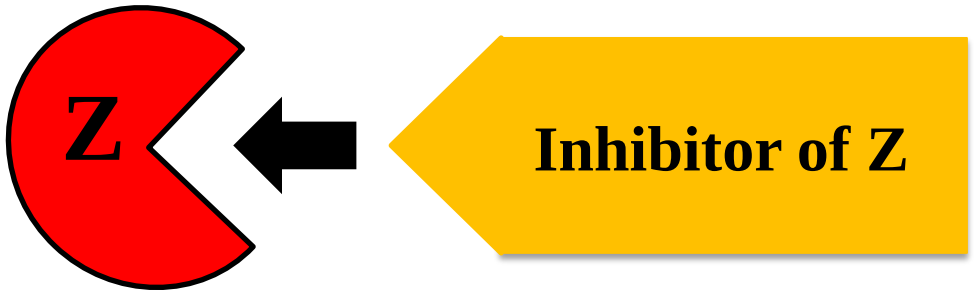
- **District Court**
  - Interpreted rapamycin as generic term
    - Encompasses any structural analog of sirolimus that exhibits immunosuppressive and anti-restenotic effects
      - Claim encompasses (at minimum) tens of thousand of compounds
- **CAFC**
  - The specification discloses only a starting point for further iterative research in an unpredictable and poorly understood field
  - **Invalid for lack of enablement**
    - Undue experimentation required to practice claimed subject matter

Take Away

- Reach-through method claims based on disclosure of relatively few compounds are regularly issued by the USPTO

- Appeals to the Board have overruled Examiners who reject reach-through method claims for lack of written description/enablement when only a few compounds are disclosed.

- CAFC has yet to rule on a Scenario 2 or 3 case
  - however, expect resistance to broad genus claims when only one or a small number of species are exemplified.



Summary: Can claim recite administering an "**Inhibitor of Z**"?

1	No known compounds	Not patentable
2	Four known compounds	Patentable; but vulnerable to invalidity attack in litigation
3	Twenty known and five new compounds	Patentable; more likely to withstand invalidity attack in litigation