

*Pfizer v. Ranbaxy:*  
**How *NOT***  
**to Write Dependent Claims**

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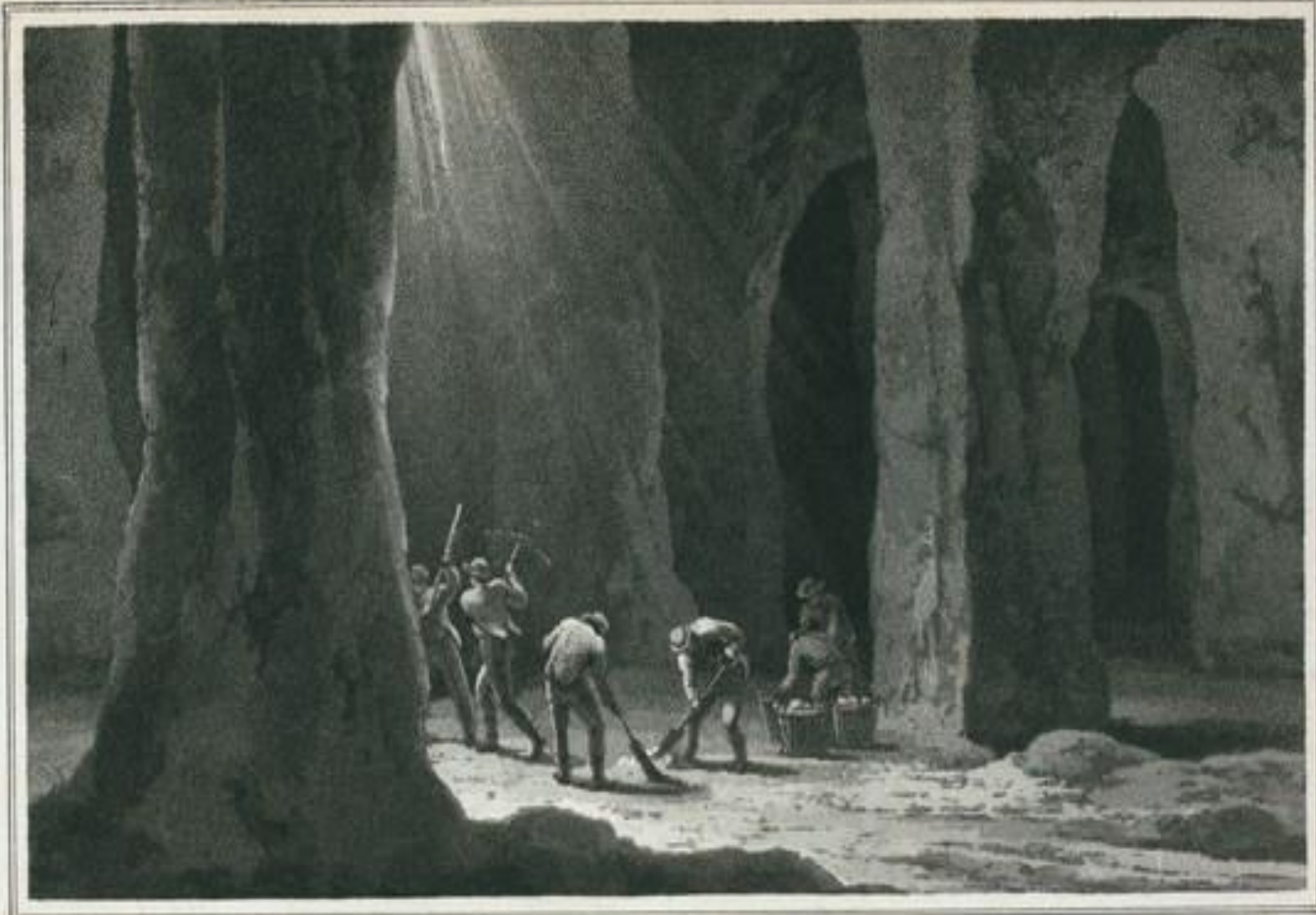
*Pfizer v. Ranbaxy*, 457 F.3d 1284, 79 USPQ2d 1583  
(Fed. Cir. 2006)

- ANDA case regarding generic Lipitor® (atorvastatin)
- Lower court found two patents *infringed* and *not invalid*
- Federal Circuit affirmed as to Pfizer's US 4,681,893 (so Ranbaxy lost in the short term)
- Federal Circuit reversed regarding validity of claim 6 of US 5,273,995

*Lessons from this case?*

## *First lesson:*

A salt is not an acid



INTERIOR OF A SALT MINE.

*Designed by W. Daniell.*

*Published by Messrs. Colburn & Turner, London, March 1827.*

## *Second lesson:*

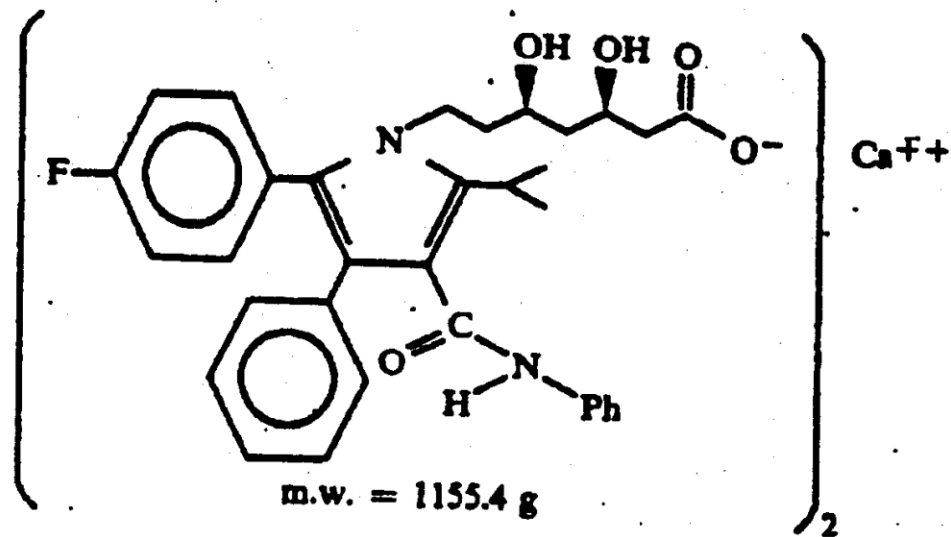
Proper dependency is a life-or-death matter

‘995 patent claims 1, 2, and 6

1. *[Atorvastatin acid or atorvastatin lactone or pharmaceutically acceptable salts thereof]*
2. A compound of claim 1 which is [*atorvastatin acid*].
6. The hemicalcium salt of the compound of claim 2.

Of this patent, Pfizer asserted only claim 6.

## Hemicalcium Salt





Ranbaxy argued claim 6 was invalid on several grounds, including for failure to comply with 35 USC § 112, paragraph 4

35 USC § 112, paragraph 4:

“Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and **then specify a further limitation of the subject matter claimed.** A claim in dependent form shall be construed to **incorporate by reference all the limitations of the claim to which it refers.**”

- Claim 6 cannot be read to “incorporate by reference all the limitations of the claim to which it refers” and “then specify a further limitation of the subject matter claimed.”

District Court said that is not a ground for invalidity.  
Federal Circuit disagreed.

- Could have written 6 to depend from 1 or as independent claim
- Precedent: *Curtiss-Wright Flow Control Corp.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006) suggested such a claim could be invalid
- No suggestion in intrinsic record that “acid” was meant to encompass corresponding salt, so unlike *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1372 (Fed. Cir. 2003)

USPTO's new 112 ¶2 examination guidelines briefly mention that this is a ground for rejection

(see page 7166 of Federal Register Volume 76, Number 27, pages 7162-7175 (February 9, 2011))

<http://www.regulations.gov/#!documentDetail;D=PTO-P-2010-0088-0001>

If you use “salt” limitation in a dependent claim, be certain salts are explicitly covered in all base claims up the chain

## *What about solvates and polymorphs?*

May depend on how independent claim is written

1. A compound of Formula A.
  - Should implicitly cover all solvates and polymorphs, unless prosecution estoppel
  - Include disclosure in specification to make that clear
2. A composition comprising a compound of Formula A.

“Infringement test” MPEP 608.01(n)(III):

Dependent claim is proper if it can't be infringed without also infringing the claim from which it depends.

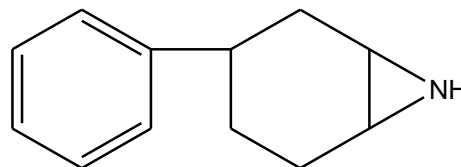
## These dependents 2-4 are OK:

1. A compound of Formula A.
2. A method of treating diabetes, the method comprising administering to a diabetic patient an effective amount of the compound of claim 1.
3. A process of making the compound of claim 1, the process comprising reacting a compound of Formula B with acetone, thereby producing the compound of claim 1.
4. A method of generating a salt, the method comprising reacting the compound of claim 1 with X, thereby generating a salt of Formula A.

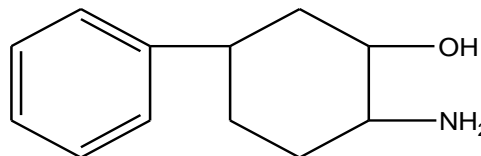


These dependents 2-3 are **NOT OK**  
(rewrite as independent)

1. A compound having the structure of Formula A:



2. The compound of claim 1, wherein the phenyl ring is substituted with a halogen.
3. An intermediate used in a process of making the compound of claim 1 and having the following structure:



**These dependents 2-5 are NOT OK  
(rewrite as independent)**

1. An isolated polypeptide consisting of SEQ ID NO: 2.
2. The polypeptide of claim 1, wherein the Ala at position 28 of SEQ ID NO:2 is replaced with a Leu.
3. A fragment of the polypeptide of claim 1.
4. An antibody that binds to the polypeptide of claim 1.
5. An isolated DNA that encodes the polypeptide of claim 1.

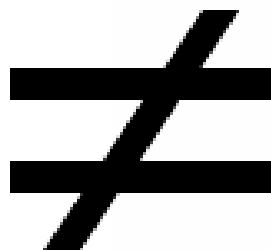
**These dependents 2-3 are NOT OK**  
**(rewrite as independent)**

1. A gizmo comprising a whozit operably linked to a whatzit.
2. A machine for assembling the gizmo of claim 1, wherein the machine comprises....
3. A whozit suitable for use in the gizmo of claim 1, wherein the whozit comprises....

## Product by process

1. A process comprising reacting X with Y for 1 hour at 80°C, thereby producing a polymer.
2. A polymer made by the process of claim 1.
  - MPEP: proper dependent claim
3. The polymer set forth in claim 1.
  - MPEP: not proper dependent claim
  - Polymer could be made by a different process, so could infringe claim 3 without infringing claim 1.

*So remember the lesson of Pfizer v. Ranbaxy...*



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