



UNIVERSITY OF  
MARYLAND  
SCHOOL OF LAW

**PATENT LAW  
UPDATE**

***Bayer AG  
v.  
Housey  
Pharms., Inc.***

No. 02-1598  
Federal Circuit  
Aug. 22, 2003

***"[I]nfringement  
under 35  
U.S.C.  
§ 271(g) is  
limited to  
physical goods  
that were  
manufactured  
and does not  
include  
information  
generated by a  
patented  
process."***

On August 22, 2003, the Federal Circuit affirmed the district court's order dismissing Housey's counterclaim for infringement of U.S. Patents No. 4,980,281, No. 5,266,464, No. 5,688,655, and No. 5,877,007, which related to protein inhibitors and activators, for failure to state a claim because the accused drug products were not "manufactured" by a process claimed in the asserted patents under 35 U.S.C. § 271(g). The Federal Circuit stated:

"[Section 271(g) provides that whoever] without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent . . . . A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product. [T]he statute [seems] concerned exclusively with products that are physical goods produced by a manufacturing process. One statutory exception to section 271(g) rules out infringement where the allegedly infringing product "is materially changed by subsequent processes." Housey's position – that information itself is a "product" – is difficult to reconcile with the existence of this exception, which appears to contemplate a change in a physical product. Similarly, the second exception to section 271(g), which provides that there is no infringement where the accused product "becomes a trivial and nonessential component of another product," also appears to contemplate a physical product. [N]othing in section 101 . . . suggests that "made" in section 271(g) should be construed to be broader than "manufacture."

The legislative history leads to the same conclusion: that Congress was concerned solely with physical goods that had undergone manufacture. . . . Even if the legislative history did not affirmatively suggest an intent to limit coverage to manufactured "articles" in accordance with section 1337, . . . nothing in the legislative history suggest[s] that Congress was concerned that the preexisting statutory scheme failed to reach intangible information, or that the substantive coverage of the Act, as opposed to the available remedies, was to be expanded. Each and every reference to the provision that became section 271(g) describes it as directed to manufacturing. . . . The legislative history's very silence thus suggests that Congress did not intend to expand coverage beyond manufactured articles.

[R]eading the statute to cover processes other than manufacturing processes could lead to anomalous results. The importation of information in the abstract (here, the knowledge that a substance possesses a particular quality) cannot be easily controlled. [A] person possessing the allegedly infringing information could, under Housey's interpretation, possibly infringe by merely entering the country. Such an illogical result cannot have been intended. [I]t is best to leave to Congress the task of expanding the statute if we are wrong in our interpretation. Congress is in a far better position to draw the lines that must be drawn if the product of intellectual processes rather than manufacturing processes are to be included . . . .