

# United States Court of Appeals for the Federal Circuit

01-1122

NOVARTIS CORPORATION,

Plaintiff-Appellant,

v.

BEN VENUE LABORATORIES, INC. and BEDFORD LABORATORIES,

Defendants-Appellees.

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Appealed from: U.S. District Court for the District of New Jersey

Judge William G. Bassler

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DECIDED: November 7, 2001

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Before CLEVINGER, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and SCHALL, Circuit Judge.

CLEVINGER, Circuit Judge.

Novartis Corporation ("Novartis") appeals from the decision of the United States District Court for the District of New Jersey granting the motion of Ben Venue Laboratories, Inc., and Bedford Laboratories ("Ben Venue") for summary judgment of noninfringement of U.S. Patent No. 4,711,880. Because we conclude that Novartis has not set forth sufficient facts to entitle it to a trial on the merits of its claim, we affirm the district court's grant of summary judgment.

## BACKGROUND

The drug pamidronate disodium (phosphonic acid (3-amino-1-hydroxypropylidene) bis-, disodium salt) is a bone-resorption inhibitor used to treat disorders of bone metabolism, including bone metastases, cancer-associated hypercalcemia, and Paget's disease. Appellant Novartis markets pamidronate disodium under the trade name Aredia. Novartis enjoyed a period of new drug exclusivity for pamidronate disodium under 21 U.S.C. § 355(c)(3)(D), based on a new indication for treatment of bone metastases in breast cancer. Novartis's period of exclusivity expired on July 16, 1999.

Novartis sells pamidronate disodium as a lyophilized solid that is reconstituted with sterile water for injection into a patient. In Novartis's formulation, the drug takes the form of pamidronate disodium pentahydrate, a crystalline material in which each molecule of pamidronate disodium occupies a defined position in a crystal lattice and is complexed with five water molecules. The water molecules bound to the pamidronate disodium in the crystal are termed the water of crystallization. Although the substance pamidronate disodium itself is unpatented, crystalline formulations of pamidronate disodium are the subject of U.S. Patent No. 4,711,880 ("the '880 patent"). The '880 patent, owned by Novartis, claims all forms of crystalline pamidronate disodium containing water of crystallization, including pamidronate disodium pentahydrate.

Appellee Ben Venue Laboratories, in the name of its subsidiary Bedford Laboratories, filed a "paper" New Drug Application (NDA 21-113)<sup>1</sup> with the Food and Drug Administration (FDA) on February 26, 1999, seeking approval for its own formulation of pamidronate disodium. Instead of Novartis's crystalline form of pamidronate disodium,

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<sup>1</sup> Similar to an abbreviated new drug application (ANDA), a paper NDA relies upon safety and efficacy data submitted by another manufacturer. See 21 U.S.C. § 355(a)(2) (1994).

Ben Venue's NDA described a liquid formulation in which the pamidronate disodium was already dissolved in water and ready for injection. Ben Venue planned to begin selling its liquid formulation when Novartis's period of exclusivity expired on July 16, 1999. Ben Venue's filing included a "Paragraph IV certification," by which a drug manufacturer seeking FDA approval of a drug claimed by a patent certifies its belief either that the patent is invalid, or that the patent will not be infringed by the manufacture, use or sale of the proposed new drug. 21 U.S.C. § 355(b)(2)(A)(iv) (1994).<sup>2</sup> Ben Venue's Paragraph IV certification asserted that since its pamidronate disodium was already dissolved in water, neither its formulation nor its manufacturing process involved the crystalline form of the drug claimed by the '880 patent.

As required by 21 U.S.C. § 355(b)(3)(A), Ben Venue notified Novartis, the patent holder, of its Paragraph IV certification. Novartis promptly filed suit against Ben Venue for infringement of the '880 patent under 35 U.S.C. § 271(e)(2)(A), which makes the filing of an NDA for a patented drug an act of infringement. By filing its lawsuit against Ben Venue within 45 days of receiving notice of Ben Venue's Paragraph IV certification, Novartis forestalled, at least temporarily, FDA approval of Ben Venue's product. 21 U.S.C. § 355(c)(3)(C) (1994). A second infringement suit, initiated by Novartis when Ben Venue amended its NDA to include a higher dosage formulation, was later consolidated into the original infringement action.

Ben Venue moved for summary judgment of noninfringement. Following discovery, the submission of expert affidavits by both sides, and oral argument, the district court granted Ben Venue's motion, holding that Novartis had failed to present any evidence that

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<sup>2</sup> For a description of the filing and certification process, see Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1244-1245, 54 USPQ2d 1710, 1712-1713 (Fed. Cir. 2000). The process is similar for a paper NDA and an ANDA.

the claimed crystalline pamidronate disodium actually forms in Ben Venue's process. Novartis appeals the district court's grant of summary judgment. We exercise our jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

I

A

Summary judgment is appropriate when, after opportunity for discovery and upon motion, there is no genuine dispute of material fact for trial and one party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). Summary judgment must be granted against a party who has failed to introduce evidence sufficient to establish the existence of an essential element of that party's case, on which the party will bear the burden of proof at trial. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). The summary judgment movant, however, has the initial responsibility of identifying the legal basis of its motion, and of pointing to those portions of the record that it believes demonstrate the absence of a genuine issue of material fact. Id. at 323. Once the movant has made this showing, the burden shifts to the nonmovant to designate specific facts showing that there is a genuine issue for trial. Id. at 324.

Since the ultimate burden of proving infringement rests with the patentee, an accused infringer seeking summary judgment of noninfringement may meet its initial responsibility either by providing evidence that would preclude a finding of infringement, or by showing that the evidence on file fails to establish a material issue of fact essential to the patentee's case. Vivid Tech., Inc. v. American Sci. & Eng'g, Inc., 200 F.3d 795, 807, 53 USPQ2d 1289, 1297 (Fed. Cir. 1999). Summary judgment of noninfringement may only be granted if, after viewing the alleged facts in the light most favorable to the nonmovant and drawing all justifiable inferences in the nonmovant's favor, there is no genuine issue

whether the accused device is encompassed by the patent claims. Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1304, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999).

When a district court grants summary judgment, we review without deference whether disputed material facts exist, and review independently whether the prevailing party is entitled to judgment as a matter of law. SunTiger, Inc. v. Scientific Research Funding Group, 189 F.3d 1327, 1333, 51 USPQ2d 1811, 1814 (Fed. Cir. 1999).

## B

The '880 patent discloses a crystalline form of pamidronate disodium, in which each molecule of the pamidronate disodium salt is complexed with five molecules of water. Unlike the forms of pamidronate disodium known in the prior art, this crystalline form is said to have a defined water content and not to absorb additional water during storage. Formulations with defined and stable water content are desirable for pharmaceuticals, since they allow for extended storage and accurate dispensation by weight. Claim 1 of the '880 patent recites pamidronate disodium in a crystalline form that contains water of crystallization. Dependent claim 3 recites the crystalline form of the drug in which five water molecules are associated with each molecule of pamidronate disodium.

For purposes of summary judgment, the parties contest neither the validity of the '880 patent nor the construction of its claims. With the agreement of the parties, the district court gave claim 1 its broadest possible scope and construed the claim to read on pamidronate disodium in any crystalline form containing water of crystallization. While the '880 patent describes other, less well-defined crystalline forms of pamidronate disodium, the parties and the district court refer to the pentahydrate crystalline form of claim 3 interchangeably with crystalline pamidronate disodium in the broader sense of claim 1, and

for purposes of summary judgment the parties seem to assume that any crystalline material formed in Ben Venue's process would be the pentahydrate form.

What is disputed by the parties narrows to a single question of fact: whether the crystalline form of pamidronate disodium exists at any point during Ben Venue's process for manufacturing pamidronate disodium in solution. Ben Venue asserts that the pamidronate disodium remains dissolved in solution throughout its manufacturing process, which would preclude the formation of any crystalline material. In contrast, Novartis contends that crystalline pamidronate disodium could form transiently at a particular step in Ben Venue's process. Because the district court did not find Novartis's expert testimony probative of events that might occur during Ben Venue's manufacturing process, the district court granted Ben Venue's motion for summary judgment of noninfringement.

## II

When a patentee seeks to block FDA approval of an NDA under 35 U.S.C. § 271(e)(2)(A), the infringement inquiry focuses on the hypothetical infringement that would occur if the defendant's NDA were approved and the defendant began to make and sell the drug. Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569, 42 USPQ2d 1257, 1263 (Fed. Cir. 1997). Ben Venue manufactures pamidronate disodium by using another compound, pamidronic acid, as its starting material. See Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 146 F. Supp. 2d 572, 576 (D.N.J. 2001).<sup>3</sup> Pamidronic acid is identical in structure to pamidronate disodium, except that the phosphate groups of the pamidronate ion are bound to hydrogen ions rather than sodium ions. As described in the '880 patent,

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<sup>3</sup> The parties have requested confidential treatment for many details of Ben Venue's manufacturing process. Those facts disclosed here are based on the published opinion of the district court cited above, on processes described in the '880 patent, on portions of the briefs and district court opinion not designated confidential, and on statements made by counsel during oral argument in open court, to which neither party has objected.

pamidronate disodium may be formed from pamidronic acid by treating pamidronic acid with a strong base such as sodium hydroxide (NaOH). In effect, the hydrogen ions bound to the pamidronate ion in pamidronic acid are exchanged for sodium ions, yielding water and the disodium salt of the pamidronate ion.<sup>4</sup>

Because pamidronic acid is only sparingly soluble in water, relatively little pamidronic acid will dissolve at neutral pH. Rather, the starting material for making pamidronate disodium from pamidronic acid usually consists of a suspension of undissolved pamidronic acid particles in water, with a small amount of pamidronic acid dissolved in solution. Concentrated NaOH is then added as the solution is vigorously mixed, thereby neutralizing the pamidronic acid and yielding pamidronate disodium.

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<sup>4</sup> No evidence in the record addresses the question of to what extent either pamidronic acid or pamidronate disodium ionizes (dissociates) in solution.

However, since acid-base reactions typically take place between molecules in solution, the NaOH in the solution primarily reacts with the small fraction of pamidronic acid molecules dissolved in solution, rather than with the solid pamidronic acid particles. Because dissolution is an equilibrium process, conversion of the pamidronic acid to pamidronate disodium allows additional solid pamidronic acid to be dissolved. This freshly dissolved material may then be neutralized by NaOH, and, assuming sufficient NaOH has been added, the reaction will continue until all the pamidronic acid has been dissolved and converted to pamidronate disodium. Thus, we may think of the manufacture of pamidronate disodium in terms of two separate but linked processes: the conversion of solid pamidronic acid to dissolved pamidronic acid, and the conversion of dissolved pamidronic acid to dissolved pamidronate disodium.

Novartis alleges that a third process occurs during Ben Venue's manufacturing scheme: the conversion of dissolved pamidronate disodium to infringing crystalline pamidronate disodium. The parties seem to agree, and the record indicates, that no crystalline pamidronate disodium is present at either the beginning or the end of Ben Venue's process. This follows from the fact that, at any given time, the total concentration of pamidronate disodium in Ben Venue's reaction vessel is well below the solubility limit of the salt. Under such circumstances, all of the pamidronate disodium will be dissolved and none will be in the crystalline form. Ben Venue's expert asserted that this condition precludes the formation of the infringing crystalline material at any and all times during Ben Venue's process.

However, the proposition that pamidronate disodium is always present below its solubility limit is true only as a bulk property of the solution. Novartis argues that the concentration of pamidronate disodium could transiently exceed its solubility limit (thereby

crystallizing) in local zones around solid pamidronic acid particles. The dispersal of NaOH into the water and the neutralization of soluble pamidronic acid by NaOH take a finite amount of time (how much time is contested fiercely by the parties). Thus, according to Novartis, solid particles of pamidronic acid remain in contact with concentrated NaOH for an appreciable length of time. Neutralization occurs as pamidronic acid dissolves from the particle surface and encounters NaOH. Near the surface of these particles, pamidronic acid enters solution, is converted to pamidronate disodium, and is then carried away from the acid particle by diffusion and mixing. If the pamidronate disodium is not carried away fast enough, Novartis theorizes that the local concentration of pamidronate disodium in a zone surrounding the particle surface might exceed the solubility limit, and the infringing pentahydrate could thereby crystallize out of solution. However, mixing and diffusion would eventually carry the crystalline material away from the acid particle into the bulk solution. There, the concentration of pamidronate disodium is well below the solubility limit, and the crystalline pamidronate disodium would dissolve, leaving behind no trace of its existence.<sup>5</sup>

To prove infringement under this theory, Novartis must demonstrate by a preponderance of the evidence that crystalline pamidronate disodium forms in a zone around an undissolved particle of pamidronic acid upon treatment with concentrated NaOH. Therefore, to withstand Ben Venue's motion for summary judgment, Novartis was

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<sup>5</sup> The theory of Novartis's case is that Ben Venue's product infringes the patent in suit even if the final product does not infringe, so long as at some time during manufacture the limitations of the claim are met. For this theory, Novartis relies on Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 30 USPQ2d 1285 (Fed. Cir. 1994) and Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 35 USPQ2d 1801 (Fed. Cir. 1995). In both of those cases, the same theory was argued by the patentee, unsuccessfully. At oral argument in this case, counsel was asked if the theory is subject to challenge since the cases relied on did not find infringement. Counsel was also asked whether the theory of infringement based on transitory existence of the patented composition, if otherwise legitimate, is misplaced in the context of a § 271(e)(2)(A) action. Because Novartis has

obliged to show that a finder of fact could reasonably find at least two propositions to be true. First, that following the addition of concentrated NaOH to a suspension of solid pamidronic acid particles, solid particles of pamidronic acid persist for an appreciable length of time and remain in contact with concentrated NaOH. Second, that near the surface of these particles, neutralization of pamidronic acid by NaOH yields enough pamidronate disodium to exceed the solubility limit and form the infringing crystalline material.

Novartis submitted the affidavits of two experts, Drs. McKenna and Nauman, as evidence that a reasonable finder of fact could find both these propositions true. Dr. McKenna performed experiments to measure, inter alia, the lifetime of a pamidronic acid particle as it dissolves in concentrated NaOH, and the time required for infringing crystalline material to precipitate from a solution already supersaturated with pamidronate disodium (i.e., a solution containing dissolved pamidronate disodium at a concentration above the solubility limit). Dr. McKenna's experiments did not address whether a supersaturated zone actually would form around an undissolved pamidronic acid particle. To establish that such a zone exists, Novartis relied upon a computer model developed by Dr. Nauman. According to Dr. Nauman, this model (a) simulates the neutralization process as it would occur around a pamidronic acid particle in contact with concentrated NaOH, and (b) predicts that amounts of pamidronate disodium in excess of the solubility limit would form around the surface of a pamidronic acid particle in a short time. Based on the model's predictions, and on his calculations of the mixing time required for Ben Venue's system to reach homogeneity after the addition of NaOH, Dr. Nauman concluded that

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failed to raise a genuine issue of material fact to resist summary judgment of noninfringement, we pursue no further these questions raised at oral argument.

infringing crystalline pamidronate disodium would temporarily precipitate out of solution before the pamidronic acid particles dissolved completely.

The district court rejected Dr. Nauman's conclusions. According to the district court, Novartis had failed to demonstrate why Dr. Nauman's computer model was representative of Ben Venue's process. Specifically, the district court questioned the applicability of a forty-year old scholarly article ("the Norwood article") upon which Dr. Nauman's model was allegedly based, and faulted Dr. Nauman for failing to consider the particular mixing equipment employed by Ben Venue. These shortcomings undermined Dr. Nauman's claim that the model accurately characterized Ben Venue's manufacturing process. Even viewing the evidence in a light most favorable to Novartis, the district court regarded Dr. Nauman's model as "so wholly deficient and empirically groundless as to not rise above the level of a self-serving conclusion." Since the predictions of Dr. Nauman's model were an essential element in Novartis's case, Novartis's failure to connect the computer model to Ben Venue's commercial process entitled Ben Venue to summary judgment.

### III

Because our review when summary judgment is granted is without deference to the district court, we have examined the evidence in record to determine whether there are genuine issues of material fact in dispute, making all inferences in favor of Novartis. Ben Venue submitted no evidence that would preclude a finding of infringement under Novartis's theory. Of course, disproving the existence of a transitory product is not Ben Venue's responsibility. Novartis must show that it could prove the existence of the infringing product at trial. Under its theory of infringement, Novartis would have to prove both that solid particles of pamidronic acid persist, and that the infringing crystalline material will form around them. We conclude that Novartis has introduced sufficient

evidence to create a genuine issue of material fact as to its first proposition, that particles of pamidronic acid remain in contact with concentrated NaOH for an appreciable length of time. Dr. McKenna's experiments and the testimony of Ben Venue's employees support this proposition. While Ben Venue levels a protean array of criticisms against this proposition, such issues as how fast Ben Venue's system reaches homogeneity, how the design of Ben Venue's mixing equipment affects the mixing calculations, and the exact dissolution rate of pamidronic acid particles, are inferences from the facts in record that must be drawn in Novartis's favor.

With regard to Novartis's second proposition--that a zone near the surface of solid pamidronic acid particles exists in which the neutralization reaction yields supersaturating concentrations of pamidronate disodium--we conclude that Novartis has not introduced evidence from which a reasonable fact-finder could conclude that this proposition is true. The only support for this essential proposition is Dr. Nauman's computer model. Novartis argues that the district court erred in dismissing Dr. Nauman's model as unrepresentative of Ben Venue's process. We agree with Novartis that the particular criticisms leveled against Dr. Nauman's model in the district court's opinion are wide of the mark. Whether Dr. Nauman took into account the exact design of Ben Venue's mixing equipment, and whether the Norwood article accurately describes Ben Venue's mixing process, relate primarily to Nauman's calculation of the time required for Ben Venue's system to reach homogeneity following NaOH addition. Dr. Nauman did not base his computer model on these calculations, and his alleged failure to take these factors into consideration thus cannot render his computer model suspect.

We believe the district court's confusion over the basis of Dr. Nauman's model was understandable, however, because the record is nearly devoid of any indication of what Dr.

Nauman did base his model on. It is this deficiency that is fatal to Novartis's case. Under modern summary judgment law, a patentee who fails to provide probative evidence of infringement runs the risk of being peremptorily nonsuited. See Celotex, 477 U.S. at 322-323. Evidence from which a reasonable fact-finder could find infringement will forestall this possibility. However, a party does not meet this evidentiary threshold merely by submitting the affidavit of an expert who opines that the accused device meets the claim limitations. Regarding such conclusory opinions, we explained in Arthur A. Collins, Inc. v. N. Telecom Ltd.:

Although such testimony of an expert witness may be proper during trial when the opposing party can challenge the factual basis of the expert's opinion during cross-examination, the affidavit of an expert submitted in opposition to a motion for summary judgment must do more by "set[ting] forth specific facts showing that there is a genuine issue for trial." Thus, the expert must set forth the factual foundation for his opinion... in sufficient detail for the court to determine whether that factual foundation would support a finding of infringement under the claim construction adopted by the court, with all reasonable inferences drawn in favor of the nonmovant.

216 F.3d 1042, 1047-1048, 55 USPQ2d 1143, 1147 (Fed. Cir. 2000) (alteration in original) (citations omitted) (quoting Fed. R. Civ. P. 56(e)). The necessity for such an explicit factual foundation should be self-evident. If all expert opinions on infringement or noninfringement were accepted without inquiry into their factual basis, summary judgment would disappear from patent litigation. We look to regional circuit law for the applicable standard, since the factual foundation necessary to support an expert's opinion is not a matter peculiar to patent law. Id. at 1048, 55 USPQ2d at 1147.

In the context of summary judgment motions, the Third Circuit has demanded that the factual predicate of an expert's opinion must find some support in the record, and has emphasized that mere "theoretical speculations" lacking a basis in the record will not create a genuine issue of fact. Penn. Dental Ass'n. v. Med. Serv. Ass'n., 745 F.2d 248,

262 (3d Cir. 1984). Moreover, where an expert's opinion is predicated on factual assumptions, those assumptions must also find some support in the record. Shaw v. Strackhouse, 920 F.2d 1135, 1142 (3d Cir. 1990). We must therefore identify the assumptions made by Dr. Nauman in his computer model, and ask whether they are supported by evidence in the record. These include both the theoretical principles that informed the model's design as well as the means by which its input parameters were derived.

The record includes only the source code for Dr. Nauman's model and two graphs that we assume represent the model's output. Each graph contains several plots, representing different time points, of predicted pamidronate disodium concentration as a function of distance from the particle center. How the input parameters were varied to yield the two different graphs is not explained. The source code for Dr. Nauman's model is reproduced in full below:

```
#include<stdio.h>
#include<iostream.h>
#include<math.h>
#include<fstream.h>
#include<string.h>
#define D 5e-10
#define radius 2.7e-4
#define blt 2.7e-4
#define k 2.7e-6
#define smax 2808
#define tmax 100
#define Pi 3.14159
#define max 100000
#define delt 1e-4
#define ones 10000
#define delx 1e-6
#define numsec 1
void itoa(char[5],int);
void reverse (char[]);
void intout(int , int, double []);
double sold[max+1], snew[max+1];
int boundary, movb, counter=0, oldb, dollarsmoved,nums;
```

```

double factor1, factor2, temp1, diff;
double xratio, centsmoved;
double stufflostnow=0, stufflosttotal=0;
main()
{
int N,M,T;
double totaldist;
totaldist=blt+radius;
N=(int)(totaldist/delx);
M=(int)(radius*N/totaldist);
T=(int)(tmax/delt);
nums=numsec*ones;
xratio=(delt*k)/delx;
movb=M;
for(int i=0;i<=N;i++)
{
sold[i]=0;
snew[i]=0;
}
factor1=D*delt/(delx*delx);
factor2=D*delt/(delx);
centsmoved=0;
for(int t=1;t<=T;t++)
{
if(movb>0)
{
oldb=movb;
centsmoved+=xratio;
dollarsmoved=(int)(centsmoved);
if(dollarsmoved!=0)
{
movb=oldb-dollarsmoved;
if(movb<0)
movb=0;
for(int i=oldb-1;i>=movb;i--)
sold[i]=smax;
centsmoved=centsmoved-dollarsmoved
}
}
for(int i=movb+1;i<=N-1;i++)
snew[i]=sold[i]*(1.0-(2.0*factor1)-
((2.0*factor2)/(i*delx)))+sold[i+1]*(factor1+(2*factor2)/(delx*i))+ sold[i-1]*(factor1);
snew[N]=0;
stufflostnow=(4.0*snew[N-1] -snew[N-2]*(D*delt*N*delx*4*Pi)/(2*delx);
if(movb!=0)
{
diff=0;
for(int i=movb+1;i<=N;i++)

```

```

diff+=(snew[i]-sold[j])*i*i*delx*delx;
double shiftdown= 0.0;
shiftdown=(diff)/(delx*delx*movb*movb)+stufflostnow/(4*Pi*delx*delx*movb*movb*d
elx); if((sold[movb]-shiftdown)>snew[movb+1])
snew[rmovb]=sold[movb]-shiftdown;
else
snew[movb]=(4.0*snew[movb+1]-snew[movb+2])/3.0;
}
else
snew[movb]=(4.0*snew[movb+1]-snew[movb+2])/3.0;
for(int j=0;j<=N;j++)
sold[j]=snew[j];
if(t%nums==0)
{
int tback=(t/ones);
intout(tback,N, snew);
cout<<tback<<"\n";
}
}
return 0;
}
void itoa(char s[5],int n)
{
int i, sign;
if((sign=n)<0)
n=-n;
i=0;
do
{
s[i++]=n%10+'0';
}
while((n/=10)>0);
if(sign<0)
s[i++]='-';
s[i]='\0';
reverse(s);
return;
}
void reverse (char s[])
{
int c,i,j;
for(i=0,j=strlen(s)-1;i<j;i++;j--)
{
c=s[i];
s[i]=s[j];
s[j]=c;
}
return;
}

```

```

}
void intout(int timer, int num, double arr[])
{
char arr_name[25], times[10];
strcpy(arr_name, "sphere_");
itoa(times, timer);
strcat(arr_name, times);
strcat(arr_name, ".dat");
ofstream out1(arr_name);
for(int i=0;i<=num;i++)
{
out1 <<arr[i]<<"\n";
}
out1.close();
return;
}

```

The program's main routine appears to begin at line 28. The astute reader will have noted that line 28 is not commented. Nor is line 29. Nor is line 30. In fact, this court has searched all the lines of Dr. Nauman's model for comment or explanation, in vain. While we concede that line 12, which defines Pi to be 3.14159, is self-explanatory even to a judge of this court, the remainder of Dr. Nauman's code is populated by inscrutably named variables such as "dollarsmoved" and "centsmoved," which may or may not represent the conditions of Ben Venue's commercial process, upon which are performed unexplained mathematical operations, which may or may not represent the dynamics of Ben Venue's neutralization reaction. Neither the basic theoretical framework nor the derivation of the necessary inputs is apparent from Dr. Nauman's source code.

Dr. Nauman's entire explanation of the basis of his model consists of the following statement:

I obtained the necessary parameters for the model from the literature (molecular weights of pamidronic acid and pamidronate disodium), from standard correlations (Atkins, Physical Chemistry, 5th Ed., p. 24, Freeman, New York, 1987; Perry, Chemical Engineering Handbook, 7th Ed., p. 2-372, McGraw Hill, New York, 1997; Sotman, et al., Kristallografiya, Vol. 35, p. 1442, 1990) and from the direct measurements cited above and in the declaration of Prof. McKenna.

The cited references appear to describe the basic equations for computing reaction rate and diffusivity. They are not specific to any reaction under question and it is unknown how Dr. Nauman employed them. One might estimate the reaction rate for dissolution of pamidronic acid from Dr. McKenna's experiments, but there is no indication how Dr. Nauman derived the rates for the neutralization or crystallization reactions, or if such rates are taken into consideration by the model. Even if we were to accept without question that Dr. Nauman began with the proper parameters, we are left completely in the dark as to how he employed them. It is also unclear if these computations require some assumptions about how the surface zone interacts with the bulk solution-- assumptions that might or might not depend on the treatment of the mixing process. Without this information, it is impossible to tell if Dr. Nauman's model accurately reflects the conditions of Ben Venue's process. Apparently, we are to accept as an article of faith that Dr. Nauman employed accepted and realistic equations or theories. Novartis makes some attempt on appeal to explain the input parameters, but even here its explanations are inadequate. Moreover, the theoretical foundation of the model remains inscrutable, and summary judgment does not demand that we refrain from any scrutiny of the nonmovant's evidence.

There is nothing inherently unreliable or suspect about computer simulations as evidence. But every simulation of a physical process embodies at least some simplifying assumptions, and requires both a solid theoretical foundation and realistic input parameters to yield meaningful results. Without knowing these foundations, a court cannot evaluate whether the simulation is probative, and it would be unfair to render an expert's opinion immune to challenge because its methodology is hidden in an uncommented computer model. Dr. Nauman's credentials are impeccable, and it is quite possible that another expert of his stature could unravel his code and deduce the assumptions,

algorithms, equations, and parameters that must be embedded within it. Indeed, it is quite possible that Dr. Nauman himself could translate the foreign language of his computer model into a comprehensible language that would permit the model to support his professional opinion of Ben Venue's infringement.

But under our law and the law of the Third Circuit, it was Novartis's obligation to set forth the detailed basis of its evidence such that the district court could evaluate whether it could support a finding of infringement by a reasonable fact-finder. Without such basis in the record, we must regard Dr. Nauman's opinion as no more than theoretical speculation raising, at best, a "metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986).

Other than Dr. Nauman's computer model, there are no facts in the record indicating that pamidronate disodium pentahydrate would crystallize out of solution in the zone surrounding the surface of an undissolved pamidronic acid particle. Since this was Novartis's only theory of how the infringing product might be created in Ben Venue's process, there is no evidence in the record that the infringing product would form in Ben Venue's proposed manufacturing process. In the absence of such evidence, Ben Venue was entitled to summary judgment of noninfringement.

If our previous opinions have not made clear the landscape of summary judgment law in infringement litigation, we do so here. Summary judgment is a trap for the unwary plaintiff. Under Celotex, a patentee may be obliged to present his or her evidence of infringement early in the litigation process. Where, as here, the theory of infringement relies on relatively esoteric and indirect means of proof, the patentee must also be prepared to provide the court with the theoretical and factual foundation underlying that

proof, at least to the extent of presenting a genuine issue of material fact to avoid summary judgment.

#### CONCLUSION

For the reasons set forth above, we agree with the district court's conclusion that Novartis's computer model was insufficiently grounded in the specifics of the accused process. We conclude that Novartis has failed to create a genuine issue of material fact as to whether the claimed product forms during Ben Venue's manufacturing process. We therefore affirm the district court's grant of summary judgment of noninfringement.

#### COSTS

No costs.

AFFIRMED