

May 4, 2021

VIA REGULAR MAIL and EMAIL

[Comments.mailbox@njcourts.gov](mailto:Comments.mailbox@njcourts.gov)

Hon. Glenn A. Grant

Acting Administrative Director of the Courts

Attention: MCL Application—Tasigna Litigation

Hughes Justice Complex, P.O. Box 037

Trenton, NJ 08611

**Re: Plaintiffs' Reply to Novartis's Supplemental Comments Regarding  
Application for Multicounty Litigation Designation for Tasigna Cases**

Dear Judge Grant:

Please accept this letter as Plaintiffs' collective response to Novartis Pharmaceutical Corporation's Supplemental Comments Regarding Application for Multicounty Litigation Designation for Tasigna Cases. Plaintiffs are compelled to file this response to correct Novartis's letter—admittedly sent outside of the comment period—which mischaracterized the statements of Judge William J. McGovern III at a recent hearing, during which he denied Novartis's motion to consolidate all Tasigna cases in Morris County.

In its letter, Novartis claims that “the Morris County Superior Court is prepared to consolidate immediately” the Tasigna cases pending in Morris County. This is not, however, what Judge McGovern said in either his Order or at the hearing. Given the opportunity to consolidate the cases before Plaintiffs' MCL application is decided, Judge McGovern denied the motion, stating: “[t]here is a *probability* that the MCL will be granted, which would neutralize any consolidation order.” See Order dated May 3, 2021 (attached to Novartis's letter), at p. 3 (emphasis added). In fact, Judge McGovern indicated he was hopeful and optimistic that the MCL application would be granted.

It is clear that the Morris County Superior Court is not, as Novartis stated, prepared to consolidate the Tasigna cases immediately. For the reasons already briefed, Plaintiffs believe the MCL is the superior process, designed precisely for this type of mass tort litigation.

Respectfully submitted,



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March 9, 2021

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**VIA FEDEX and EMAIL**

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Hon. Glenn A. Grant  
Acting Administrative Director of the Courts  
Attention: MCL Application – Tasigna Litigation  
Hughes Justice Complex, P.O. Box 037  
Trenton, New Jersey 08611

**KELLY JONES HOWELL**  
MEMBER  
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**Re: Application for Multicounty Litigation Designation for Tasigna® Cases**

Dear Judge Grant:

This firm, along with Hollingsworth<sup>LLP</sup>, represents Defendant Novartis Pharmaceuticals Corporation (NPC) in all cases filed in New Jersey involving Tasigna<sup>®</sup> -- a cancer medication used to treat cancer chronic myeloid leukemia (CML). Tasigna<sup>®</sup> is the only medicine that currently is FDA-approved to provide the possibility of allowing patients to cease treatment for CML if certain treatment goals are met. These cases are the subject of a January 19, 2021 *Rule 4:38A* application for Multicounty Litigation (MCL), which is currently pending before the New Jersey Supreme Court. NPC opposes the creation of an MCL for Tasigna<sup>®</sup> cases for the reasons set forth below. In the event the Supreme Court determines MCL designation is appropriate and does not deem Morris County to be an appropriate venue, NPC agrees with Bergen County as the MCL vicinage.

**Introduction**

While NPC agrees with plaintiffs that a form of consolidation could be appropriate for the collection of pending cases involving Tasigna<sup>®</sup>, NPC opposes an MCL designation. An MCL is unnecessary and would not create meaningful efficiencies that cannot be obtained via an intra-county consolidation in Morris County – where all of the cases were initially filed by plaintiffs, and where ninety-six of the ninety-nine current cases remain as of the date of this response. Since the first case was filed nearly a year ago in March 2020, these cases have been successfully managed in Morris County Superior Court. Morris County is the location of NPC’s headquarters, its witnesses, and relevant corporate documents. Morris County is where the parties have worked together cooperatively for the past year to develop discovery schedules, negotiate discovery disputes, and advance these cases efficiently and expeditiously without significant court time. There has been nothing to suggest that these cases cannot continue moving forward in Morris County. Under the circumstances, MCL designation and assignment to another vicinage would nullify the progress made in Morris County to date in these cases, and introduce unnecessary delays to their ultimate resolution.

Rather than an MCL designation, the best course here is for the cases to remain in plaintiffs’ chosen filing venue and for the Court in Morris County to coordinate matters as it determines is appropriate. That would allow the cases to remain in the most logical and appropriate venue,

protect against the potential burdens and delays associated with MCL designation, and provide the plaintiffs with the benefits of consolidated litigation they seek. To that end, NPC is moving in Morris County to consolidate all Tasigna<sup>®</sup> cases pending there and will seek a hearing in Morris County as necessary once the MCL Application is decided. NPC has filed its motion in the hopes of presenting its proposed course of action to all of the interested judicial and administrative bodies for consideration and uniform resolution.

In the event the Supreme Court determines MCL designation is appropriate and does not deem Morris County to be an appropriate venue, NPC consents to Bergen County as the MCL site.

### **Procedural History**

The first Tasigna<sup>®</sup> case in New Jersey was filed on March 16, 2020, in Morris County. Nine more cases were filed there that month. From April 1 to December 22, 2020, forty-five cases, an average of five per month, were filed by plaintiffs, all in Morris County. On December 22, three plaintiffs filed Tasigna<sup>®</sup> cases in Morris County, then quickly dismissed and refiled them in their respective home counties of Essex, Ocean, and Camden counties. Between December 22, 2020, and January 19, 2021, thirteen plaintiffs filed new Tasigna<sup>®</sup> cases – all in Morris County. On January 19, 2021, counsel for all plaintiffs applied for MCL designation in Bergen County.<sup>1</sup> Since the Application was filed, thirty-four additional plaintiffs have filed cases in New Jersey – again, all in Morris County. On March 9, NPC filed a Motion for Consolidation in Morris County seeking consolidation of all Tasigna<sup>®</sup> cases pending there (attached as Exhibit A).<sup>2</sup> As of this filing, there are ninety-nine Tasigna<sup>®</sup> cases pending in New Jersey state courts. Ninety-seven percent of those cases are currently pending in Morris County (96 of 99). Approximately ninety-three percent of the Tasigna cases filed in New Jersey state court involve plaintiffs from outside New Jersey (92 of 99). The plaintiffs in these cases are all represented by the same small group of experienced law firms. NPC is the sole defendant. Again, all of these cases were initially filed in Morris County.

### **Background**

This litigation involves NPC's product, Tasigna<sup>®</sup> – a tyrosine kinase inhibitor (TKI) medication that is FDA-approved to treat patients with chronic myeloid leukemia. CML is a relatively uncommon cancer with only about 8,000 new cases each year in the United States. Tasigna<sup>®</sup> is one of five TKIs that doctors use to treat CML. It is highly effective in treating CML by targeting the genetic basis of the cancer, with long-term overall survival approaching that of age-matched controls. In other words, the majority of CML patients treated with Tasigna<sup>®</sup> now have a close to normal life expectancy – even though CML had a less than 5-year expected survival rate prior to the development of TKIs. Tasigna<sup>®</sup> is a “second-generation” TKI, initially approved in 2007. Compared to its predecessor, Tasigna<sup>®</sup> results in earlier response, higher response rates, and lower

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<sup>1</sup> This followed plaintiffs' first indication that they were considering applying for an MCL designation during a December 9, 2020 Case Management Conference in the matter *Chase v. NPC* (Docket No.: MRS-L-748-20).

<sup>2</sup> If the plaintiffs' MCL application is denied and consolidation in Morris County granted, NPC may move for transfer to Morris County in the only three cases not currently pending there.

risk of CML progression to advanced stages that lead to bad outcomes, most notably, death. Tasigna<sup>®</sup> is the only CML therapy with data supporting an FDA-approved label detailing how Tasigna<sup>®</sup> can suppress CML enough to allow some patients to discontinue CML therapy – something called treatment-free remission (TFR). Tasigna<sup>®</sup> thus presents an opportunity for possible remission of the cancer CML without undergoing further anti-cancer therapy. Even with significant advances in life expectancy resulting from revolutionary TKI treatments like Tasigna<sup>®</sup>, there are only about 58,000 patients with diagnosed CML in the United States at any given time.

Plaintiffs generally allege that Tasigna<sup>®</sup> causes atherosclerotic-related injuries and that NPC failed to provide adequate warnings regarding that potential risk to their prescribing oncologists. From the first FDA approval of Tasigna in 2007, the label has warned about cardiac-related adverse events in patients treated with Tasigna<sup>®</sup> – including sudden death and QT prolongation in a boxed warning, as well as coronary artery disease in the “Adverse Reactions” section. NPC first recognized a possible signal for peripheral arterial occlusive disease (PAOD) in Tasigna<sup>®</sup> users in 2010, disclosed this to the FDA in March 2011, and since November 2011, Tasigna<sup>®</sup>’s FDA-approved labeling has warned of reports of PAOD in patients treated with Tasigna<sup>®</sup> in the “Adverse Reactions” section of the label. In January 2014, NPC revised the label to include reports of Cardiac and Vascular events in patients treated with Tasigna<sup>®</sup> in the “Warnings and Precautions” section of the Tasigna labeling. At all times, NPC has provided adequate warnings regarding the available data on cardiovascular events that have occurred in patients receiving Tasigna<sup>®</sup>.

### **Argument**

#### **I. MCL Designation is Unnecessary: Morris County is an Appropriate and Capable Venue.**

Plaintiffs’ selection of Morris County as the initial filing vicinage for all of these cases is compelling evidence that Morris County is the most logical and appropriate venue for the Tasigna<sup>®</sup> Litigation. Presumably to enhance their counsel’s argument for MCL designation, three plaintiffs who initially filed in Morris County voluntarily dismissed their cases and refiled in other counties (Essex, Ocean, and Camden), where they reside. Nevertheless, ninety-six of the ninety-nine cases (97%) filed in New Jersey state court remain in Morris County, where the plaintiffs voluntarily chose to file. Additionally, cases filed since the motion for MCL designation have, without exception, been voluntarily filed in Morris County. That this overwhelming majority of cases were filed in Morris County is not surprising. Nearly all of the cases involve out-of-state plaintiffs (92 of 99), making Morris County – NPC’s headquarters and principal place of business – the only venue in New Jersey with any connection to ninety-three percent of the cases. Notably, of the seven cases involving New Jersey resident plaintiffs, only three were re-filed in the residents’ home counties – an apparent attempt to dodge any argument that there is no multi-county aspect to the litigation rather than a reflection that plaintiffs view Morris County as an inappropriate venue. Convenience also favors Morris County as corporate documents and corporate witnesses likely to be involved in this case are located in Morris County at NPC’s headquarters, making it

the most convenient location for many witnesses. Simply put, Morris County is the only venue with a connection to all of the filed cases. It is the most logical, most appropriate, and most convenient venue for the Tasigna<sup>®</sup> cases.

Ninety-eight plaintiffs are represented by the same New Jersey law firm, Parker Waichman LLP, with some plaintiffs also having additional out-of-state co-counsel. NPC is represented by the undersigned counsel and Hollingsworth<sup>LLP</sup>. Together, the parties, and the small group of attorneys representing them, have developed a productive and cooperative working relationship. This has allowed the parties to negotiate and submit agreed-upon pretrial schedules when required, without exception. The schedules all include periodic Case Management Conferences, which will serve to keep the Courts in Morris County apprised of the parties' progress.

The parties have also made significant progress in discovery over the past year. Collectively, the parties have served approximately eighty-nine sets of written discovery across dozens of cases. Since last June 2020, NPC has provided plaintiffs with more than 480,577 documents that equate to more than ten million pages, consisting of, among other things, over 100,000 company emails from 14 custodians, the Tasigna<sup>®</sup> regulatory file and organizational charts dating back to 2007, and the identities of numerous individuals involved in the internal evaluation of issues related to cardiovascular events. NPC has also collected 88,000 pages of medical records from plaintiffs' healthcare providers. These cases are poised to move into deposition discovery in earnest. An MCL, which would presumably require new scheduling orders and the restart of fact discovery, would negate the substantial progress made to date and potentially delay resolution of these cases. There is nothing to suggest that handling the cases in Morris County cannot continue to work well moving forward.

The benefits that plaintiffs seek through MCL designation can be provided by intra-county consolidation in Morris County. To the extent plaintiffs seek to have a single judge decide issues that will have litigation wide impacts, any of the judges in Morris County who currently have Tasigna<sup>®</sup> cases would have the experience to handle litigation of this nature and can decide such issues, bolstered by their familiarity with the cases and the parties. Morris County has experience successfully designing and managing processes for consolidating a group of alike cases brought by multiple plaintiffs against a single defendant.

The Supreme Court should, therefore, decline to create an MCL for the Tasigna cases and allow the judges of Morris County to continue to efficiently and effectively manage these cases, either individually or (at the County's choice) via intra-county consolidation.

**II. If the MCL Application is Granted, NPC Does Not Oppose Plaintiffs' Vicinage Request.**

If the Supreme Court determines that an MCL designation is appropriate and the cases should be removed from Morris County, NPC agrees with plaintiffs that Bergen County is suitable and does not oppose plaintiffs' vicinage request.


**Conclusion**

NPC opposes MCL designation because the cases can be efficiently and effectively litigated in Morris County – the most convenient and most logical venue for these cases. NPC is moving in Morris County for consolidation to address plaintiffs’ desire to have the cases coordinated, alleviating any burden to plaintiffs from a denial of their MCL application. Because MCL designation is not necessary or beneficial, the application should be denied.

Dated: March 9, 2021

Respectfully submitted,

**HARRIS BEACH PLLC**

By:   
Kelly Jones Howell, Esq.  
Marina Plotkin, Esq.

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Cc: { via email }

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# **EXHIBIT A**

Kelly Jones Howell (State Bar ID # 030682005)  
Marina Plotkin (State Bar ID # 047582005)  
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Attorneys for Defendant Novartis Pharmaceuticals Corporation

\_\_\_\_\_  
THERESA DALTON,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Defendant.  
\_\_\_\_\_

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION, MORRIS COUNTY

DOCKET NO.: MRS-L-000662-20

CIVIL ACTION

**NOTICE OF MOTION TO  
CONSOLIDATE**

TO: Clerk, Superior Court of New Jersey  
Morris County Administration Building  
56 Washington Street  
Morristown, New Jersey 07960

TO: ALL COUNSEL ON SERVICE LIST ATTACHED TO CERTIFICATION OF  
SERVICE

**PLEASE TAKE NOTICE** that the undersigned, attorneys for the Defendant, Novartis Pharmaceuticals Corporation (NPC), shall move before the Superior Court of New Jersey, Law Division, Morris County, on **April 30, 2021** at 9:00 a.m., or as soon thereafter as counsel may be heard, for an Order consolidating for discovery purposes only, this matter with other matters brought by various plaintiffs against NPC and currently pending in Morris County regarding NPC's product, Tasigna<sup>®</sup>. A list of all matters pertaining to this motion, including discovery end

dates and other motion checklist information, is annexed as Exhibit A to the Certification of Kelly Jones Howell, Esq., dated March 9, 2021.

**PLEASE TAKE FURTHER NOTICE** that in support of the instant motion, counsel for NPC will rely upon the enclosed Certification of Kelly Jones Howell, Esq., and Memorandum of Law.

**PLEASE TAKE FURTHER NOTICE** that pursuant to R. 1:6-2(d), the undersigned requests oral argument. A proposed form of Order is attached.

Pertaining to *Dalton v. Novartis*, MRS-L-000662-20 (earliest filed case), the current Discovery End Date is July 30, 2021. There is current no set trial date. The matter is being case managed by Judge William J. McGovern and there is no case management conference scheduled.

Dated: March 9, 2021

Respectfully submitted,

**HARRIS BEACH PLLC**

By: 

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Andrew L. Reissaus, Esq. (*Pro Hac Vice*)  
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*Attorneys for Defendant  
Novartis Pharmaceuticals Corporation*

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Attorneys for Defendant Novartis Pharmaceuticals Corporation

\_\_\_\_\_  
THERESA DALTON,  
  
Plaintiff,

v.

NOVARTIS PHARMACEUTICALS  
CORPORATION,  
  
Defendant.

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION, MORRIS COUNTY

DOCKET NO.: MRS-L-000662-20

CIVIL ACTION

**ORDER CONSOLIDATING ACTIONS**

**THIS MATTER** having been opened before the Court by Harris Beach, PLLC, attorneys for Defendant, Novartis Pharmaceuticals Corporation (NPC), for an Order for Consolidation, and the Court having considered the moving papers and any opposition thereto, and for good cause shown:

**IT IS** on this \_\_\_\_\_ day of \_\_\_\_\_, 2021,

**ORDERED** that Defendant's motion is hereby **GRANTED**; and it is further

**ORDERED** that this matter and the matters brought by plaintiffs against NPC in Morris County asserting claims related to NPC's product, Tasigna<sup>®</sup>, current list annexed as Exhibit A, are hereby consolidated in the Superior Court of New Jersey, Law Division, Morris County, under

Docket No. MRS-L-000662-20, for discovery purposes only (Consolidated Actions); and it is further

**ORDERED** that all papers filed in the Consolidated Actions shall include the caption *Theresa Dalton v. Novartis Pharmaceuticals Corporation*, Docket No. MRS-L-000662-20, with a note in caption “*Applies to Cases Listed on Schedule A*”; and it is further

**ORDERED** that service of a true and correct copy of this Order shall be deemed effectuated upon all parties upon its upload to eCourts.

Pursuant to Rule 1:5-1(a), movant shall serve a copy of this Order on all parties not served electronically within seven days of the date of this Order.

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J.S.C.

\_\_\_\_\_ Opposed

\_\_\_\_\_ Unopposed

Kelly Jones Howell (State Bar ID # 030682005)  
Marina Plotkin (State Bar ID # 047582005)  
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Attorneys for Defendant Novartis Pharmaceuticals Corporation

THERESA DALTON,  
  
Plaintiff,

v.

NOVARTIS PHARMACEUTICALS  
CORPORATION,  
  
Defendant.

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION, MORRIS COUNTY

DOCKET NO.: MRS-L-000662-20

CIVIL ACTION

**CERTIFICATION OF KELLY JONES  
HOWELL, ESQ. IN SUPPORT OF  
MOTION FOR CONSOLIDATION**

I, Kelly Jones Howell, Esq., hereby certify that:

1. I am an attorney-at-law of the State of New Jersey and a partner of the law firm of Harris Beach PLLC, attorneys for Defendant, Novartis Pharmaceuticals Corporation (NPC). I am one of the attorneys charged with the responsibility of defending these matters, and, as such, I am fully familiar with the relevant facts.

2. I submit this Certification in support of Defendant's Motion for Consolidation of this matter with all matters pending in Morris County asserting claims related to Defendant's product, Tasigna<sup>®</sup> for discovery purposes.

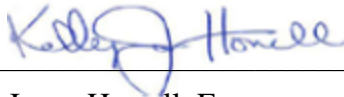
3. Attached hereto as **Exhibit A** is a true and accurate copy of a list of the matters pending in Morris County asserting claims related to Defendant's product, Tasigna<sup>®</sup>.

I certify that the foregoing statements made by me are true and correct. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: March 9, 2021

Respectfully submitted,

**HARRIS BEACH PLLC**

By: 

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Andrew L. Reissaus, Esq. (*Pro Hac Vice*)  
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Attorneys for Defendant Novartis Pharmaceuticals Corporation

\_\_\_\_\_  
THERESA DALTON,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Defendant.  
\_\_\_\_\_

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION, MORRIS COUNTY

DOCKET NO.: MRS-L-000662-20

CIVIL ACTION

**MEMORANDUM OF LAW IN SUPPORT OF NOVARTIS PHARMACEUTICALS  
CORPORATION'S MOTION TO CONSOLIDATE**

**Introduction**

Pursuant to Rule 4:38, Defendant Novartis Pharmaceuticals Corporation (NPC) respectfully submits this brief in support of its motion to consolidate before this Court all cases pending in Morris County asserting claims related to its product, Tassigna®.

Since March 2020, beginning with the above-captioned plaintiff, ninety-nine plaintiffs have filed lawsuits in the Superior Court of Morris County alleging injury related to NPC's product, Tassigna® – a tyrosine kinase inhibitor (TKI) medication that is FDA-approved to treat patients with chronic myeloid leukemia (CML). Those cases are pending before Judges Ramsey,



Minkowitz, McGovern, Franzblau, and Bogaard. In December 2020, three plaintiffs who had originally filed their cases in Morris County voluntarily dismissed them and re-filed in Essex County, Ocean County, and Camden County respectively.<sup>1</sup> Those are now the only three Tasigna<sup>®</sup> cases in New Jersey state court pending outside of Morris County. Ninety-eight plaintiffs are represented by the same New Jersey law firm, Parker Waichman LLP, with some plaintiffs also having additional out-of-state co-counsel.<sup>2</sup>

Morris County is the only venue with any connection to all of the filed cases. NPC's headquarters is located within the county in East Hanover, making it a proper venue pursuant to Rule 4:3-2. Ninety-three percent of the pending cases involve out-of-state plaintiffs, and, of the cases remaining in Morris County, no New Jersey county is the residence of more than a single New Jersey resident.

All of the cases have been assigned to Civil Track III for discovery end date purposes. In the ninety-six remaining Morris County cases, the judges handling the cases have all allowed the parties to collaborate on creating schedules for the interim pretrial discovery deadlines. To date, the parties have worked cooperatively to submit agreed-upon schedules in the cases, without exception. The schedules all provide dates for periodic Case Management Conferences at which the various courts have been kept abreast of the parties' progress. Additionally, Michael Eisner, Esq., who has been tasked with overseeing discovery in many Morris County cases, is in regular communication with the parties across all cases regarding case status.

Given the posture of litigation involving Tasigna<sup>®</sup> and the length of time many of these cases have been pending, significant progress has been made in the cases. Both parties have served

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<sup>1</sup> If consolidation is granted in Morris County, NPC will move to transfer venue to Morris County in those cases so that they may be consolidated here as well.

<sup>2</sup> A chart listing all 96 cases pending in Morris County is attached as **Exhibit A** to Certification of Kelly Jones Howell, Esq. dated March 9, 2021.

and responded to written interrogatories and document requests in dozens of cases. Through a prior Tassigna<sup>®</sup> case in another jurisdiction, NPC has already provided plaintiffs with more than 480,577 documents that equate to ten million pages consisting of, among other things, over 100,000 company emails from 14 custodians, the Tassigna<sup>®</sup> regulatory file and organizational charts dating back to 2007, and the identities of numerous individuals involved in the internal evaluation of issues related to cardiovascular events. NPC has also collected over eighty-eight thousand pages of medical records for the various plaintiffs. Having collected the requisite records, NPC is ready to proceed with the depositions of plaintiffs in the earliest filed cases, and has requested their availability.<sup>3</sup>

Despite the fact that these cases are moving forward appropriately here in plaintiffs' chosen venue – Morris County, plaintiffs applied for Multicounty Litigation (MCL) designation with the New Jersey Supreme Court (NJSC) and requested that the cases be transferred to Judge Rachelle Harz in Bergen County. NPC is opposing plaintiffs' MCL application on the grounds that these cases can be consolidated in Morris County and handled most conveniently and effectively here without the need for MCL designation.<sup>4</sup> NPC seeks consolidation of these cases in Morris County now so that they are best positioned to be efficiently litigated until the NJSC makes its determination on MCL designation. And so that the cases can move forward seamlessly in the event that the NJSC concludes that MCL designation is not warranted.

These cases satisfy the criteria for consolidation under Rule 4:38, and consolidation in Morris County would be in the best interest of efficiency, convenience, and fairness to the parties.

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<sup>3</sup> Those cases are: *Dattilo v. NPC*, No. MRS-L-730-20; *Myers v. NPC*, No. MRS-L-747-20; *Nakamoto v. NPC*, No. MRS-L-890-20; *Burnett v. NPC*, No. MRS-L-920-20; and *Dalton v. NPC*, No. MRS-L-662-20.

<sup>4</sup> In its opposition to plaintiffs' MCL application, NPC intends to request that in the event the Supreme Court deems MCL designation appropriate, that MCL be placed in Morris County.

Accordingly, NPC requests that this Court enter an Order consolidating all Tasigna® cases currently pending in Morris County.

### **Background**

In these product liability actions, plaintiffs seek damages alleging “injuries resulting from Novartis’ intentional failure to warn of dangerous and known risks associated with Tasigna.” Compl. ¶ 1. Tasigna® and the class of TKI medications, of which it is a member, have revolutionized the treatment of CML – a cancer that occurs when the blood-forming cells of the bone marrow make too many white blood cells, including immature ones. CML is a relatively uncommon cancer with only about 8,000 new cases each year in the United States. Tasigna® is one of five TKIs that doctors use to treat CML. Without treatment, CML can progress from a chronic phase to an accelerated phase, and finally to blast crisis. In blast crisis, more than thirty percent of the cells in the blood or bone marrow are immature and non-functioning blast cells, and patients develop progressive weakness, weight loss, fever, and an enlarged spleen. Life expectancy for a patient in blast crisis is less than 12 months. Mortality increases as the disease progresses, but occurs at all phases of the disease.

TKIs like Tasigna® are highly effective in treating CML, with long-term overall survival approaching that of age-matched controls.<sup>5</sup> In other words, the majority of CML patients treated with Tasigna® now have a close to normal life expectancy – even though CML had a less than 5-year expected survival rate prior to TKIs.<sup>6</sup> Tasigna® is a “second-generation” TKI initially approved in 2007.<sup>7</sup> Compared to its predecessor (also developed by NPC), Tasigna® results in

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<sup>5</sup> See James A. Kennedy, MD, PhD and Gabriela Hobbs, MD *Tyrosine kinase inhibitors in the treatment of chronic phase CML: strategies for frontline decision-making* (June 1, 2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6023770/>.

<sup>6</sup> See Leukemia – Chronic Myeloid – CML: Statistics (January 2020), <https://www.cancer.net/cancer-types/leukemia-chronic-myeloid-cml/statistics#:~:text=Due%20in%20large%20part%20to,mid%2D1970s%20to%2069%25>.

<sup>7</sup> See 2007 Tasigna label, [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2007/022068s000\\_LBL.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2007/022068s000_LBL.pdf).

earlier response, higher response rates, and lower risk of CML progression to advanced stages that lead to bad outcomes, most notably, death.<sup>8</sup> Tasigna<sup>®</sup> is the only CML therapy with data supporting an FDA-approved label detailing how Tasigna<sup>®</sup> can suppress CML enough to allow some patients to discontinue CML therapy – something called treatment-free remission.<sup>9</sup> Even with significant advances in life expectancy resulting from revolutionary TKI treatments like Tasigna<sup>®</sup>, there are only about 58,000 patients with diagnosed CML in the United States at any given time.

Plaintiffs generally allege that Tasigna<sup>®</sup> causes atherosclerotic-related injuries and that NPC failed to provide adequate warnings regarding that potential risk to their prescribing oncologists. At all times, NPC has provided adequate warnings regarding the available data on cardiovascular events that have occurred in patients receiving Tasigna<sup>®</sup>. From the first FDA approval of Tasigna in 2007, the label has warned about cardiac-related adverse events— including sudden death and QT prolongation in a boxed warning, as well as coronary artery disease in the “Adverse Reactions” section. NPC first recognized a possible signal for peripheral arterial occlusive disease (“PAOD”) in 2010, and since November 2011, Tasigna<sup>®</sup>’s FDA-approved labeling has warned of reports of PAOD in patients treated with Tasigna<sup>®</sup> in the “Adverse Reactions” section of the label. In January 2014, NPC revised the label to include a “Warnings and Precautions” section titled “Cardiac and Vascular Events”.<sup>10</sup>

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<sup>8</sup> See Hochhaus A, et al. *Long-term benefits and risks of frontline nilotinib vs imatinib for chronic myeloid leukemia in chronic phase: 5-year update of the randomized ENESTnd trial*, <https://www.nature.com/articles/leu20165>.

<sup>9</sup> *Novartis drug Tasigna<sup>®</sup> is approved by FDA as first and only CML therapy with Treatment-free Remission data in its label*, Novartis.com (Dec. 22, 2017), <https://www.novartis.com/news/media-releases/novartis-drug-tasigna-approved-fda-first-and-only-cml-therapy-treatment-free-remission-data-its-label#:~:text=Students%20and%20Scholars,Novartis%20drug%20Tasigna%C2%AE%20is%20approved%20by%20FDA%20as%20first,Remission%20data%20in%20its%20label>.

<sup>10</sup> Letter from Edvardas Kaminskas, Deputy Director, U.S. Food and Drug Administration to Katie Chon, Director, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation, NDA 022068/S-017 (Jan. 22, 2014), [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2014/022068Orig1s017ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/022068Orig1s017ltr.pdf) and [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/022068s017lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022068s017lbl.pdf) (labeling information and enclosure to Jan. 22, 2014 letter).

## Argument

### **I. THE TASIGNA<sup>®</sup> CASES MEET THE CRITERIA FOR CONSOLIDATION UNDER RULE 4:38-1.**

New Jersey Court Rule 4:38-1 governs the consolidation of related actions. In pertinent part, R. 4:38-1 states:

“When actions involving a common question of law or fact arising out of the same transaction or series of transactions are pending in the Superior Court, the court on a party’s or its own motion may order the actions consolidated.”

In every complaint, plaintiffs assert that Tasigna<sup>®</sup> caused their alleged injuries without providing specific details about when or how the alleged conditions manifested. *See e.g.*, Compl. ¶ 49. Plaintiffs further allege that the Tasigna<sup>®</sup> label did not “adequately warn of the risks of atherosclerotic-related conditions associated with the drug” in the period before or during the time the plaintiff used Tasigna<sup>®</sup>. *Id.* at ¶ 50. The alleged injuries vary among plaintiffs, but each person ultimately claims they suffered an atherosclerotic-related injury due to their use of Tasigna<sup>®</sup>.

Based on plaintiffs’ complaints, there are some common questions of law and fact across the cases. Foremost, the issue of general causation – does Tasigna<sup>®</sup> increase the risk of alleged CVEs – is common to all cases (although there will be differences depending on which CVE each plaintiff alleges). Additionally, while it will not be uniformly relevant to all plaintiffs depending on their dates of use, the regulatory and labeling history for Tasigna<sup>®</sup> is an issue to be addressed in fact discovery across all cases. For these reasons, the Tasigna<sup>®</sup> cases currently pending in Morris County should be consolidated.

### **II. EFFICIENCY, CONVENIENCE, AND FAIRNESS COUNSEL IN FAVOR OF CONSOLIDATION.**

Under Rule 4:38-1, a Court is enabled to join together pending actions in the interest of promoting judicial efficiency. For several reasons, consolidation of the Tasigna<sup>®</sup> cases in Morris County would be in the best interest of efficiency, convenience, and fairness.

This Court has processes in place for bringing together like cases filed by multiple plaintiffs against one defendant for purposes of discovery that could be quickly and easily implemented here. The Morris County judiciary has the experience to handle litigation of this nature. There are at least five judges who are familiar with these cases and the parties. The cases could be easily consolidated and assigned to one of those judges for discovery. This would promote efficiency in the use of judicial resources as multiple judges would not have to hear and make rulings on the same issues. This would also promote convenience for the parties where there may be issues that can be resolved in a single instance, rather than multiple times in multiple cases. Finally, these cases are no longer in their infancy and consolidation would allow the parties to continue to efficiently capitalize on the significant progress made to date.

Consolidation of these cases is also fair to all parties and would not result in prejudice to plaintiffs. It would avoid undue delay as the cases are already being litigated here. The venue is obviously convenient for plaintiffs as it is the original filing venue in every case, and ninety-six percent of the cases remain here. Additionally, the benefits of centralized management that plaintiffs seek to avail themselves of in an MCL – most notably rulings by one judge – can be achieved by consolidation here.

Accordingly, the Rule 4:38 criteria for consolidation are met here and this Motion is due to be granted.

### **Conclusion**

For the foregoing reasons, NPC respectfully requests that the Court grant its Motion to Consolidate before the Superior Court of New Jersey, Law Division, Morris County, and for such other relief as the Court deems proper pursuant to 4:38-1.

Dated: March 9, 2021

Respectfully submitted,

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**CERTIFICATION OF SERVICE**

I certify that on this 9th day of March 2021, I electronically filed Novartis Pharmaceuticals Corporation's Motion to Consolidate with the Clerk of the Court by using eCourts. I further certify that a true and correct copy of Novartis Pharmaceuticals Corporation's Motion to Consolidate was served upon the following counsel via electronic mail:

All Counsel on Attached Service List

A handwritten signature in blue ink that reads "Kelly Jones Howell". The signature is written in a cursive style with a large initial "K" and "H".

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Kelly Jones Howell, Esq.

Dated: March 9, 2021



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# **Exhibit “A”**

	Case Name	NJ Superior Court	Discovery End Date	Case Management Conference	Judge	Complaint Filed
1	Dalton	MRS-L-000662-20	7/30/2021		McGovern	3/16/2020
5	Dattilo	MRS-L-000730-20	7/30/2021		Franzblau	3/23/2020
6	Myers	MRS-L-000747-20	7/24/2021		Ramsay	3/26/2020
7	Chase	MRS-L-000748-20	9/24/2021		Ramsay	3/26/2020
8	Cook	MRS-L-000749-20			Ramsay	3/26/2020
9	Smith	MRS-L-000750-20			McGovern	3/26/2020
10	McGillis	MRS-L-000850-20			McGovern	4/10/2020
11	Nakamoto	MRS-L-000890-20	8/14/2021		Ramsay	4/16/2020
12	Burnett	MRS-L-000920-20	8/19/2021		Franzblau	4/22/2020
13	Horowitz	MRS-L-001015-20	9/4/2021		Franzblau	5/7/2020
14	Sells	MRS-L-001044-20	9/10/2021		Ramsay	5/13/2020
15	Trigili	MRS-L-001061-20	9/11/2021		McGovern	5/15/2020
16	Bodle	MRS-L-001081-20	9/1/2021		Minkowitz	5/19/2020
17	Kelly	MRS-L-001088-20	9/17/2021		McGovern	5/20/2020
18	Invencion	MRS-L-001283-20	10/15/2021		Minkowitz	6/18/2020
19	Nunn	MRS-L-001421-20	11/7/2021		Franzblau	7/10/2020
20	Pendleton	MRS-L-001427-20	11/10/2021		Franzblau	7/13/2020
21	Tracy	MRS-L-001428-20	11/10/2021		Franzblau	7/13/2020
22	Binkley	MRS-L-001502-20	11/20/2021		Bogaard	7/23/2020
23	Castleman	MRS-L-001520-20	11/24/2021		Franzblau	7/27/2020
24	Mott	MRS-L-001553-20	11/27/2021		McGovern	7/31/2020
25	Dekeyzer	MRS-L-001554-20	11/27/2021		McGovern	7/31/2020
26	Chowbay	MRS-L-001588-20	12/5/2021		McGovern	8/7/2020
27	Hensley	MRS-L-001589-20	12/5/2021		McGovern	8/7/2020
28	Raxter	MRS-L-001598-20	12/5/2021		Bogaard	8/10/2020
29	Fenner	MRS-L-001599-20	12/5/2021		Bogaard	8/10/2020
30	Rider	MRS-L-001662-20	12/17/2021		McGovern	8/18/2020
31	Mashmoor	MRS-L-001663-20	12/16/2021		McGovern	8/18/2020
32	Pavri	MRS-L-001698-20	12/22/2021		Bogaard	8/24/2020
33	Johnson	MRS-L-001738-20	12/26/2021		Ramsay	8/31/2020
34	Post	MRS-L-001977-20	1/29/2022		Minkowitz	10/2/2020
35	Martin	MRS-L-001978-20	1/29/2022		Minkowitz	10/2/2020
36	Wingfield	MRS-L-002065-20	2/9/2022		McGovern	10/13/2020
37	Rosa	MRS-L-002066-20	2/9/2022		McGovern	10/13/2020
38	Tieskotter	MRS-L-002146-20	2/18/2022		Ramsay	10/22/2020
39	Owens	MRS-L-002202-20	2/26/2021		Bogaard	10/29/2020
40	Iverson	MRS-L-002222-20	3/2/2022		Franzblau	11/2/2020

41	Kammerer	MRS-L-002294-20	3/9/2022		Bogaard	11/9/2020
42	Floyd	MRS-L-002295-20	3/6/2022		Bogaard	11/9/2020
43	Enriquez	MRS-L-002296-20	3/9/2022		Bogaard	11/9/2020
44	Blake	MRS-L-002357-20	3/12/2022		McGovern	11/13/2020
45	Overturf	MRS-L-002358-20	3/12/2022		McGovern	11/13/2020
46	Shuster	MRS-L-002404-20	3/16/2022		Bogaard	11/19/2020
47	Endicott	MRS-L-002405-20	3/17/2022		Bogaard	11/19/2020
48	Vohra	MRS-L-002446-20	3/23/2022		Ramsay	11/24/2020
49	Shrope	MRS-L-002447-20	3/23/2022		Ramsay	11/24/2020
50	Nurse	MRS-L-002489-20	3/30/2022	5/12/2021	McGovern	12/1/2020
51	Fugate	MRS-L-002526-20	4/3/2022	5/12/2021	Franzblau	12/4/2020
52	Johnson	MRS-L-002527-20	4/3/2022	5/12/2021	Franzblau	12/4/2020
53	Stanton	MRS-L-002583-20	4/9/4022	5/12/2021	Minkowitz	12/11/2020
54	Bergold	MRS-L-002654-20	4/20/2022	6/16/2021	McGovern	12/22/2020
55	Niabes	MRS-L-002662-20	4/21/2022	5/12/2021	McGovern	12/23/2020
56	Schartz	MRS-L-002663-20	4/21/2022	5/12/2021	McGovern	12/23/2020
57	Duvall	MRS-L-002664-20	4/21/2022	5/12/2021	McGovern	12/23/2020
58	Sandmann	MRS-L-002681-20	4/27/2022	6/16/2021	Minkowitz	12/28/2020
59	Chinook	MRS-L-002682-20	4/27/2022		Minkowitz	12/28/2020
60	Morgan	MRS-L-002703-20	4/29/2022	6/16/2021	Bogaard	12/30/2020
61	Leavens	MRS-L-002704-20	4/29/2022	6/16/2021	Bogaard	12/30/2020
62	Jones	MRS-L-000064-21	5/13/2022	6/16/2021	McGovern	1/14/2021
63	Khattak	MRS-L-000096-21	5/18/2022	6/16/2021	Bogaard	1/19/2021
64	Worthey	MRS-L-000146-21	5/25/2022		Ramsay	1/25/2021
65	Duran	MRS-L-000172-21	5/26/2022		Minkowitz	1/27/2021
66	Russell	MRS-L-000182-21	5/27/2022		Minkowitz	1/28/2021
67	Pickman	MRS-L-000183-21	5/27/2022		Minkowitz	1/28/2021
68	Linton	MRS-L-000184-21	5/27/2022		Minkowitz	1/28/2021
69	Hahn	MRS-L-000223-21			Franzblau	2/3/2021
70	Olson	MRS-L-000224-21			Franzblau	2/3/2021
71	Moore	MRS-L-000225-21			Franzblau	2/3/2021
72	Hess	MRS-L-000269-21			Minkowitz	2/9/2021
73	Lloyd	MRS-L-000270-21			Minkowitz	2/9/2021
74	Broyles	MRS-L-000271-21			Minkowitz	2/9/2021
75	Vaughan	MRS-L-000313-21			Franzblau	2/12/2021
76	Douglas	MRS-L-000314-21			Franzblau	2/12/2021
77	Fisher	MRS-L-000315-21			Franzblau	2/12/2021
78	Oldham	MRS-L-000316-21			Franzblau	2/12/2021
79	Dresser	MRS-L-000325-21			Franzblau	2/16/2021
80	Wallace, Peggy	MRS-L-000326-21			Franzblau	2/16/2021
81	Turner	MRS-L-000327-21			Franzblau	2/16/2021

82	Zell	MRS-L-000328-21			Franzblau	2/16/2021
83	Littlefield	MRS-L-000338-21			Ramsay	2/17/2021
84	Pack	MRS-L-000339-21			Ramsay	2/17/2021
85	Erlich	MRS-L-000340-21			Ramsay	2/17/2021
86	Martin, K	MRS-L-000383-21			Minkowitz	2/23/2021
87	Bishop	MRS-L-000384-21			Minkowitz	2/23/2021
88	Gutierrez	MRS-L-000395-21			Bogaard	2/24/2021
89	Trudeau	MRS-L-000396-21			Bogaard	2/24/2021
90	Lavergne	MRS-L-000397-21			Bogaard	2/24/2021
91	Wallace, G	MRS-L-000407-21			Bogaard	2/25/2021
92	Gentry	MRS-L-000408-21			Bogaard	2/25/2021
93	Pace-Antonetz	MRS-L-000409-21			Bogaard	2/25/2021
94	Dunn	MRS-L-000415-21			Franzblau	2/26/2021
95	Tallant	MRS-L-000459-21			McGovern	3/4/2021
96	Pevzner	MRS-L-000460-21			McGovern	3/4/2021